From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Copy of the Prototype Consumer Reporting System for Patient Safety Events
Date:	Tuesday, November 13, 2012 9:23:23 AM
Attachments:	Consumer Reporting System for Patient Safety - Comments.docx News Release_SOS Release 053110.pdf Online+SOS_One+Page+Description+with+Logo+100212.docx Online+SOS_One+Page+Description_River+Oaks+Hosp.docx Complaint or Grievance Process HRMC.pptx PEP narrative.docx

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From: douglas.dotan@gmail.com [mailto:douglas.dotan@gmail.com] **On Behalf Of** Douglas Dotan
Sent: Friday, November 09, 2012 4:51 PM
To: Lefkowitz, Doris C. (AHRQ)
Cc: Elizabeth A. Smith, PhD; Matthew C. Mireles, MPH, PhD; Anngail Smith; AHRQ Smith, Elizabeth; Erel Joffe, MD
Subject: Re: Copy of the Prototype Consumer Reporting System for Patient Safety Events

Hi Doris,

Attached please find severl documents in response to Dr. Clancy's request for Comment. We do NOT recommend that this project be funded as proposed. On the other hand we DO recommend that such a program be made available in a totally different, more effective and much less costly format - in fact such a program already exists ustilizing modern technology and lean thinking.

If you are interested in the technology we can send you the video of the technolgy and methodolgy we recommend that AHRQ supports. It leverages social media for medicine.

Best wishes,

Douglas

On Wed, Oct 31, 2012 at 8:41 AM, Lefkowitz, Doris C. (AHRQ) <Doris.Lefkowitz@ahrq.hhs.gov> wrote:

From: douglas.dotan@gmail.com [mailto:douglas.dotan@gmail.com] **On Behalf Of** Douglas Dotan
Sent: Sunday, October 28, 2012 4:47 PM
To: Lefkowitz, Doris C. (AHRQ)
Cc: Elizabeth A. Smith, PhD; Matthew C. Mireles, MPH, PhD; Anngail Smith; AHRQ Smith, Elizabeth; Erel Joffe, MD
Subject: Copy of the Prototype Consumer Reporting System for Patient Safety Events

Dear Doris,

Please send us a copy of the proposed collection plans, data collection instruments, and specific details on the estimated burden.

The PSO Services Group and its partners would like to review and comment on ther proposed system. We have had a similar system in place for several years. It has been refined and expanded and is now called the 3-D PEP or 3 Dimesional Patient Experience Program integrating patient experience input

and caregiver recorded with an event form. We believe that our existing program already meets the proposed project requirements. We would like to verify that we are correct by reviewing the proposal before submitting our comments.

We apreciate your prompt response.

Best wishes,

Douglas

Best wishes,

Douglas

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"Communicating from the Bedside to the Boardroom"

www.crgmedical.com

Consumer Reporting System for Patient Safety

August 30, 2012 Request for Comments by Dr. Carolyn Clancy

Response by Douglas B. Dotan, MA, CQIA, Executive Director, PSO Services Group, LLC

November 9, 2012

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following:

(a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility;

We at the PSO Services Group, LLC, an AHRQ listed Patient Safety Organization have two partnering companies, a not for profit 501 (C) (3) The Community Medical Foundation for Patient Safety and CRG Medical, Inc. a Healthcare IT company both based in Houston, Texas feel that the proposed collection of information, if collected and used in the appropriate manner will have practical utility. We do not feel that it is the proper performance of AHRQ health care research and health care information dissemination. Our research and experience, even though not heavily funded, shows that patient information will be best collected and acted upon at the local level by each individual hospital and/or hospital system.

It is not accurate to state that a system to conduct the function of 'patient reporting' does not exist. In the year 2006, the ***Community Medical Foundation for Patient Safety*** worked with the ***Texas A&M Rural and Community Healthcare Institute - RCHI*** on ***PatientSpeak***, a precursor to the ***SOS Share-Our-Stories*** program. SOS was in development since 2006 and copyrighted in 2006. Around 2009, the Foundation came close to installing SOS at Twelve Oaks (River Oaks) Hospital (two sites) for patients and staff to report stories. The hospital shut down within days of launching the system. The leaders of the Foundation were asked to serve as an independent member of the hospital's patient safety committee. They wanted to include information and forms at admission. At the same time, CRG Medical, Inc. offered an electronic version of KBCore SOS. It was officially announced June 1, 2010. See attached press Release.

Because the organizations knew that the purpose of collecting patient stories was to improve patient care, it was imperative to have a single system where patient stories, complaints/grievances and event reports all went to a centralized patient experience review entity to coordinate patient centered care. The entire burden of the collection and analysis of this data should be the responsibility of the providers of care NOT the Agency for Healthcare Research and Quality. The lessons learned should be shared with the existing Patient Safety Organizations in a Common Format and shared with AHRQ and the NPSD via the PSO PPC. These organizations already exist and creating another government program that is founded on 'failure' to perform and punitive in

nature rather than on preventive, non-punitive action is what is needed. Funding should be given to organizations that can do a better job, in real-time and at a much lower cost. This proposed program is a waste of time and funds, particularly when it can be executed by people already on the ground more effectively and will be sustained over time.

(b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information;

We know from experience that the proposed costs are approximately 50% higher that can be performed by the PSO Services Group and its strategic partners. CRG Medical, the developer of the SOS, Automated PSO Common Formats, and a HCAHPS provider provides services for surveying by phone 900 patients for 300 completes a year for $6,000.

(c) ways to enhance the quality, utility, and clarity of the information to be collected;

The attached briefing sheets for patients demonstrate how the SOS process is conducted. The patients at pre-admission to the hospital are given a sign in code to the hospital's intranet. They are briefed that the PEP – Patient Experience Program exists. They are told how to use SOS to communicate with the quality staff over the computer, cell phone during their stay or after their release. They are told to tell their stories about their experience with staff – good or not so good as it may be. The quality staff can then respond in real-time, just as in the TPS system and address patient needs and continually improve the delivery of care. Staff can review daily if patient stories correlate with reports by staff. This matching of events/complaints/and patient experience will contribute daily to coordinated care and better, less costly outcomes. Ultimately we will have much higher HCAHPS score too.

(d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

The PSO Services Group has worked with two of its technology partners, CRG Medical Inc. and the iHealthExchange that provides a safe communication platform for the Health Information Exchange – HIE (iHealth Trust) to develop the KBCore Mobile CF (Common Formats) for use in a mobile device or on a desktop to communicate information rapidly and accurately. This same technology can be used by patients to share their stories. The PEP (Patient Experience Program) is accessible today at the Hunt Memorial District in Greenville, Texas for their patients. This can be the beta site for all hospitals in the country – it has already been funded – why waste public money on a system that has not been tried and because it is about failures, will probably fail itself?

These comments are being submitted in response to this notice. We trust they will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. We recommend that the request NOT be submitted as

proposed. The approach does not solve the problem. Following are comments on inaccuracies/omissions in the document that reviewers may consider.

I. Introductory Pages for Website

p. 1, second paragraph--no mention of nurses in group of people who can report, doctors, hospitals and pharmacists as an example, but nurses are in near constant contact with patients (90% of the time) and are the major caregivers, and, they are the most likely to report.

p. 3, have to be 18 years or older. Obviously, this is for adults, but what about children. There should be a comment that this system can be used by anybody to report on anybody. The same things happen to children as to adults, so why not include reporting of any person, including children, by an adult or some person capable of reporting.

2. Attachment "B"

p. 1, no need to program any pop up that says they've left something blank. They need to put something in each blank to show that they read the question and read the entire series of questions. Such as, put a * or – or n/a if it does not apply. Some people may just answer a few questions and the report will be unusable.

p. 2, statement that the report should take about 10-15 minutes is contradicted by the average of 25 minutes on p. 2 of the above document.

p. 6. There are 6 "wrongs" for medication, only 2 are listed, and "something else" is given, but I have no idea of the drop-down menu.

p. 9, 3.5 "best guess is OK"?? Important information such as day of week, time (shift change), etc. would be helpful

p. 11, 4.1 medical device not mentioned

p. 12, 4.5 "guessing" is not OK'

p. 17, 5.1 add No communication for square #5 and add contradictory communication for square F

p. 18, 5.4.1 add patient advocate for square F

p. 20, 6.2 curious about if you are not male or female, what are you?

p. 20, 6.2 there are thousands of people over 100, unless you have a space limitation allow 3 spaces

p. 20, 6.5

p. 21, 6.8 add cell phone at ____ and later use kiosk as a reporting location

p. 22, 6.9 add to items: 1) public service radio or TV and 2) educational program

3. FAQs – inappropriate wording, all negative, not helpful to the "patient"

Did not make specific comments on the next 7 of 10 sections.

In general Drs Smith and Mireles discussed the proposal:

1. The title of the reporting system is Consumer Reporting System for Patient Safety. It would appear that some consumer would be reporting for the patient, which is stated to be a doctor, pharmacist (nurse left out in introductory section).

2. Consumer is a person who uses products, and needs tangible products for their welfare—food, shelter, protection, etc. Of the organizations, services represent 85+% of GNP and products about 15%. The assumption made in the survey is that health care is a product.

Consumer, client, and patient are interchanged. Little focus on the use of the word "patient".

Following are from

3. 4.1. has finally listed medical device only once, and it never appears again

4. no way to learn if the event was a near miss

5. no way to determine anything positive that could be used for best practices

6. 4.2 "What kind of negative effect does the patient experience" – physical, emotional or both??? No other categories. If physical or both, then go to the laundry list of possibilities, i.e., breathing, numbness, etc. Emotional effect totally omitted from this category. Illogical checking of boxes. Section 5 now asks questions about why the negative affect or a mistake was made and what the patient did afterwards. There is no possibility to report that if you have a medical mistake that you would experience a negative effect

7. 4.11 is misplaced should be the last question in section #5

8. Problem in numbering, Section 5, sequence as presented is 5.4 followed by 5.4.1, which is then followed by 5.4.

9. Accepted, standard U.S. census categories for race are not used. These are standard, easy to locate, and used in all legitimate surveys and other research are not used for race. These categories appear in all government research.

10. Medical mistake, safety concern (medical mistake and injuries related to health care), and negative effects (harmed by medical care, such as infection, drug reaction, or complication) all used interchangeably, adding to confusion in general. Difficult for the patient to differentiate. No contributing factors included.

Notes From Matthew Mireles, PhD:

1. Global interpretation: format, structure and logic for the questions introduce inconsistency, and skip patterns that are extremely confusing, i.e., 4.3 question some of the choices for responses should be mutually exclusive, and they do not to eliminate confusion in the responses. Where did the negative effect first happen?: a) emergency department, b) hospital, c) doctor's office in the clinic (not mutually exclusive).

2. It would be very difficult to cross-reference a particular report to any other standard incident reporting within the hospital.

3. Tremendous emphasis on physical negative effects, very little about emotional effects.

4. Free textbox allowance = 100 (what – characters or words?)

5. Totally omitted any data on actual harm or injury. Did not ask what the injury was, as though all injuries are the same. They treat injury as injury, nothing more, with no question about severity, disability, etc. The only injuries you can have are injury to your eye or your teeth, but has a drop-down menu that does not include other body parts.

6. Very questionable regarding validity (asking what really needs to be asked) and how information can be used with any thought of reliability (consistency). Can't match patient through cross-referencing. Overlapping response categories, not mutually exclusive and confusing.

7. The categories should be defined using standard AHRQ nomenclature. On pages where there may be questions, definitions should be repeated.

8. Recommendation: Sit down with representatives from hospitals and patients and justify every piece of information that they are trying to capture. Some questions seemed bizarre and extraneous, and need to compare this to other systems to aid in the understanding of an incident.

9. Restructure some of the skip patterns and flow of the questionnaire, what could be done to prevent this was misplaced, and more logical construction of the questions would be helpful.

10. Revisit every drop box responses provided for any particular question and based on standard construction of questions, get your categories (not randomly) from sound documentation, do a literature survey. If responses are to mutually exclusive, see they are mutually exclusive.

11. Extreme reliability and validity concern regarding of what is reported. If could use email to check key questions, and the later telephone information is consistent (reliable). There should have been a concise premise and logic regarding exactly what the goal of the survey was. There is no way to

determine whether there is a medical mistake and no harm. Is this defined as a "near miss" this is a technicality. The near miss may be defined as an actual negative effect on the patient.

12. There are numerous other observational case scenarios, e.g., nurses arguing in the hallway, this is a safety concern. Think your doctor is incompetent before surgery. Huge problem with near miss—can't separate or capture this information.

From Elizabeth Smith, PhD:

1. It is very unlikely this reporting system will be used. Patients will object to the inconsistencies, poor formatting, redundancies, particularly the telephone survey. No doctor will ever respond due to the length. This is no competitor for KBCore/SOS. To redo these documents will take considerable time, if it is done at all.

2. From the view of someone who has extensive experience on how to create surveys, test instruments, etc., these documents are not even at the undergraduate level.

Community Medical Foundation for Patient Safety
The Community of Competence™ and Foundation for Life

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NEWS RELEASE

FOR IMMEDIATE RELEASE

Patients Can Go Online to Record and Share their Most Recent Medical Experiences

(BELLAIRE, TEXAS – June 1, 2010) The nonprofit Community Medical Foundation for Patient Safety, a research group specializing in patient safety research and education, has partnered with CRG Medical, Inc., an industry leader in health information technology based in Houston, to design and introduce a new recording system specifically for patients and their families.

Share Our Stories© (SOS) emphasizes the need and importance of listening to patients and learning from their wide range of experiences. Community Medical Foundation developed SOS in 2006 and presented it to the National Patient Safety Foundation Congress almost one year before the National Patient Safety Goal (NPSG) #13 was established to promote the engagement and participation of patients and their families in their own health care. Despite NPSG #13 and other efforts, patients and families rarely have a way to share their concerns and stories about an adverse event during the delivery of their care.

CRG Medical, Inc. first developed and introduced KBCore℠, an advanced web-based application to record problems as they occur at the bedside and study adverse events and near misses to improve patient safety and healthcare quality. As an Application Partner with *InterSystems,* CRG Medical, Inc. provides the only system of its kind that uses *Cache*™ to integrate patient safety information within and between hospital systems. CRG Medical, Inc. has provided the technical design and platform that make SOS available and accessible to virtually everyone and every patient around the world**.** KBCore SOS℠ is the product of this partnership with Community Medical Foundation and now one of many outstanding patient safety modules of KBCore℠.

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-- MORE --

When KBCore SOS[SM] went live, Douglas Dotan, President of CRG Medical, Inc., stated, "This is a major stride in giving all patients a voice and the means to engage and participate in health care." Each year more than one million American patients are harmed by preventable medical errors, and more than 98,000 hospital patients died from these errors.

Founder of Community Medical Foundation Elizabeth A. Smith, PhD, also believes patients and families have credible stories about their most recent experiences, good or bad, about our healthcare system that must be recorded and studied. "Stories from patients and families can only enrich our knowledge of how and why our system is failing and, perhaps, how it can be improved when these stories are coming from the greatest stakeholders and the only true customers of health care," according to Smith. Lisa Lindell, a patient safety advocate and author of the book *108 Days* commented, "If the auto and other industries are listening to their customers and designing safer, better quality products and systems, why shouldn't health care do the same for patients?"

CRG Medical, Inc. provides the technical support for KBCore SOS[SM], and Community Medical Foundation analyzes each story for valuable information, such as important lessons learned or suggestions given by patients. All stories will be used strictly for research and evaluation. No personal identifiers will be disclosed or published. The information from this new patient safety recording system will be compiled into the Foundation's *National Patient Safety Registry*. A dedicated website has been set up at **https://sos.crgmedical.com/sos/app/comm/login.jsf**. Patients and families who wish to share a recent medical story or a suggestion for improvement may log on with username: **patient** and password: **safety**. Interested hospitals may contact CRG Medical, Inc. (www.crgmedical.com) to obtain their unique login account information for their patients.

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About Community Medical Foundation for Patient Safety

Community Medical Foundation for Patient Safety, established in December 2003 as nonprofit 501 (c)(3) tax-exempt, active learning organization based in the Houston area, is a leader in patient safety research and education. Our mission is to *promote and support patient safety through research, education, and the demonstrated practice of patient-centered health care.* On behalf of the Secretary of the U.S. Department of Health and Human Services, the Agency for Healthcare Research and Quality has recognized and listed Community Medical Foundation for Patient Safety as Patient Safety Organization #29.

CRG **Medical**

Web-based Healthcare Applications

A Concern is always an Opportunity before it becomes a Grievance

From our conversation…

- Complaint / Grievance Process
  - Hunt currently uses multiple means of capturing and recording concern and or complaint information
  - Meditech is the primary modalities used by nursing staff
  - Distribution, Escalation, ad progress tracking are largely manual driven processes
  - Timeliness of response can make the difference between a concern being addressed as a complaint or requiring more extensive and expensive handling as a grievance per TJC/CMS requirements
- Current Request of CRG Medical
  - Demonstrate how current process can be electronically automated
  - Demonstrate potential enhancements to process and system logic that can be used to improve ease / effective capture, workflow tracking, alerts, transparency, reporting, accountability, consolidation of documentation/analysis and recurrence prevention.

Included in this deck

- The Process of Capture
  - Steps 1-4
- The Communication Process
  - Step 5
- Ensuring Timely Follow-up and Documentation (as req)
  - Routing
  - Alerts
  - Reporting

HUNT REGIONAL MEDICAL CENTER

KBCore Complaint

STEP ONE

- 1. What is Being Reported?
- 2. Summarize Complaint/Grievance
- 3. Immediate Actions Taken?
- 4. How could this be prevented in the future? (omit?)
- 5. How preventable was the event? (AHRQ code)(omit?)

Step 2
Patient Information

- 6. Who was involved? (ex patient /volunteer/visitor)

  Last name First Name

  Medical Record #

  Date of birth

  Gender (code)

  At the time of the event, what was the age range? (code- non-patients)

  Complaint/Grievance Received from:

  Contact information if not a patient

  Relationship: (code from form)

- 7. Name of attending physician: can be from a list (omit?)

- 8. If patient related, select unit or area where patient is housed/belongs. (code)

- 9. Clinical service (code)

Step 3

- 10. Event Unit (code)
- 11. Were any other departments involved? (code)
- 12. Date of Occurrence
- 13. Time of Occurrence
- 14. Specific location of occurrence, ex bedside, hallway (code) (omit?)

Step 4

- 15. Which of the following categories were associated with the complaint? (code)
- 16. What were the factors that contributed to this complaint? (code) (omit?)
- 17. Which of the following interventions were performed? (code) Note: codes # 3
- Severity (extent of harm) (code)

Step 5
Follow up actions for patient

- 18. What internal contacts were made? (code from form)
- Name of Physician Notified
- 19. What follow-up actions were taken? (code)

<u>Reporter Information</u>

- 20. Reporter's name

  Report Date and time
- 21. Reporter's Job or Position (code)

Follow-up Routing and Alerts Supervisor

Routed to supervisor/ manager by selection of drop down list

Name date and time (documented by system)

- Comments
- Immediate Actions taken/ Additional Internal Contacts (updated)
- Resolution: code- Resolved/ Not resolved
  - Name
  - Date and Time
- Routed to other Department supervisor/manager and Service Excellence/ CNO by selection of drop down list

  Name Date and Time note: comments in a shared space
- Routed to Director by selection of drop down list
  - Date
  - Sent by:
- ALERT sent to Director/CNO after 7 days no follow-up

  Reminder letter by selection of drop down list
  - Date and Time
  - Sent by:

Follow-up Routing and Alerts Director Level

- Comments
- Resolution
  - Satisfactory, forwarded to CNO/CEO
    - Name Date and time
  - *Un*satisfactory, returned to Dept
    - Name Date and time

- Departmental Level Resolution
  - Name
  - Date and Time

- Returned to Department for additional info by Director
  - Date
  - Sent by:

- Resolution satisfactory after further investigation requested, issue forwarded to CNO/CEO
  - Name Date and time

- ALERT sent to CNO after 7 days no follow-up from Director
  Reminder letter by selection of drop down list
  - Name
  - Date
  - Sent by:

Follow-up Routing and Alerts CNO/CEO

- Findings (same as Meditech Statement of Resolution)
- Actions/Recommendations
  - Issue Resolved, Forward to DQM
  - Written Response Sent within 30 Days
  - QC Subcommittee Convened
    - Name
    - Date and time

Communication to Patient

- Letter to Patient/family of case pending if resolution not possible within 7 days
  - Name of person sending
  - Department
  - Date
- Letter to Patient/family of findings
  - Name of person sending
  - Department
  - Date

DQM Documentation

- Complaint/Grievance Filed in Complaint Log
- Patient & Family Complaint/Grievance Form Completed
- Letter Sent to Patient/Family
- Copy of completed form and response letter to DQM
- DQM to report to QC, MEC and GB
- Name Date and time for each

Contact Information

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CRG **Medical**

Web-based Healthcare Applications

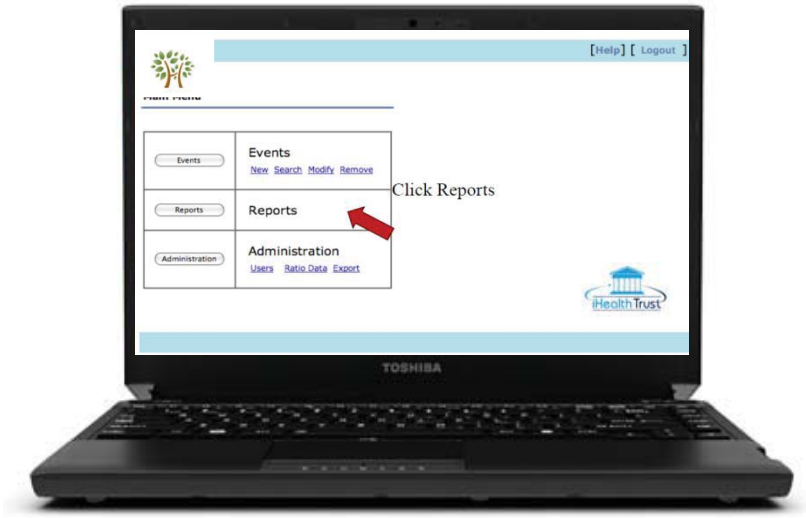
Design Process

1. Automating the Paper Process

HRMC desktop Icon

Tell Me More

IHX Portal showing
- New entry
- Mgt Follow up
- Reporting etc



Initial Entry / Capture

Patient & Family Complaint/Grievance Report Form

CONFIDENTIAL AND PRIVILEGED HEALTHCARE QUALITY IMPROVEMENT INFORMATION PREPARED IN ANTICIPATION OF LITIGATION

This document is prepared for use by the Hospital's PI Committee, a peer review and quality improvement committee established pursuant to the facility's by-laws, and in accordance with JCAHO standards, to improve the quality of care in the facility. Accordingly, in order to preserve the confidentiality and privilege of information in this document, do not distribute this document to persons who are not members of the faci1ity's PI Committee or Governing Board, absent advice and approval from Kindred's Law Department.

Step 1 Complete Complaint/Grievance Data

Patient Name (required)
First name Last name

MD (required)
First name Last name

Room Number (required)

Room Number (required)

Accepts numeric values only. Use a dot (.) for the decimal point.

Complaint/Grievance Received From: (required)
First name Last name

Relationship (required)
- Patient
- Physician
- Staff Member
- Family/ S.O. (specify below)
- Other: (specify below)

Family/ S.O.
specify relationship if applicable

Other
specify relationship if applicable

Summarize Complaint/Grievance: (required)

Date: (required)
Call placed to Risk Management designated phone line.

Click to choose a date from the calendar.

Time: (required)
Call placed to Risk Management designated phone line.

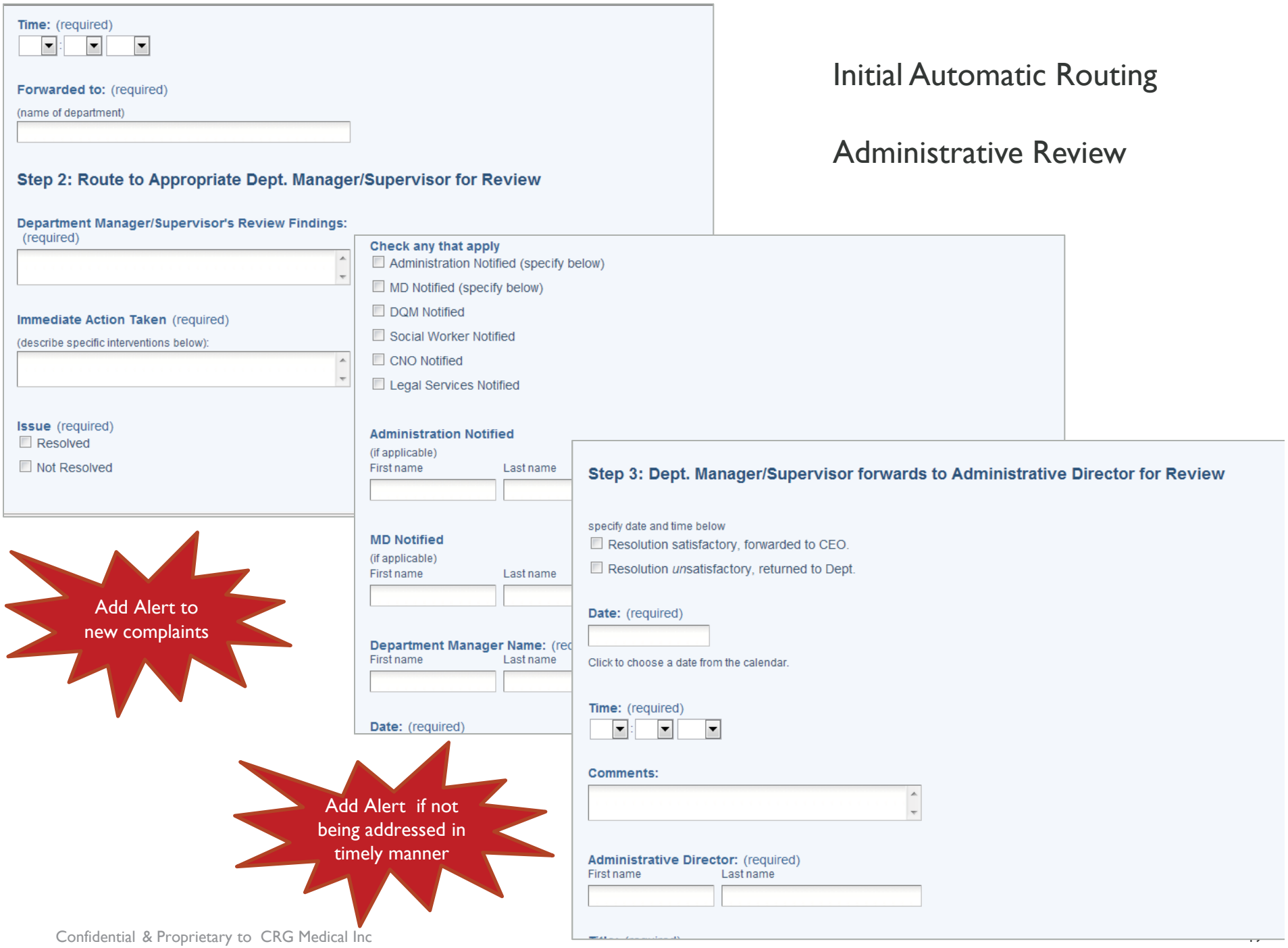
Staff Member Completing Step 1 (required)
First name Last name

Staff Member Title (required)

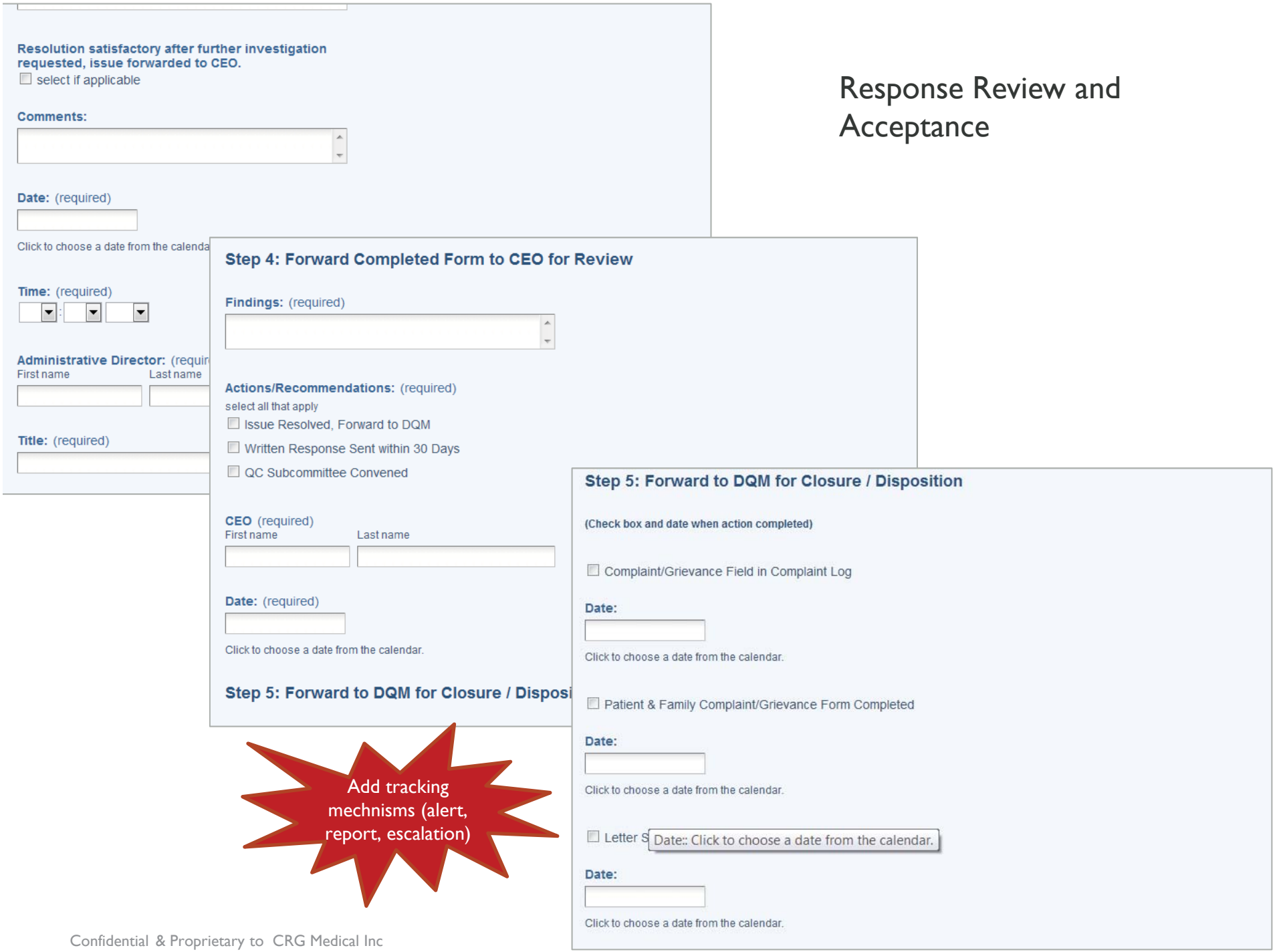
Date: (required)

Initial Automatic Routing

Administrative Review



Response Review and Acceptance

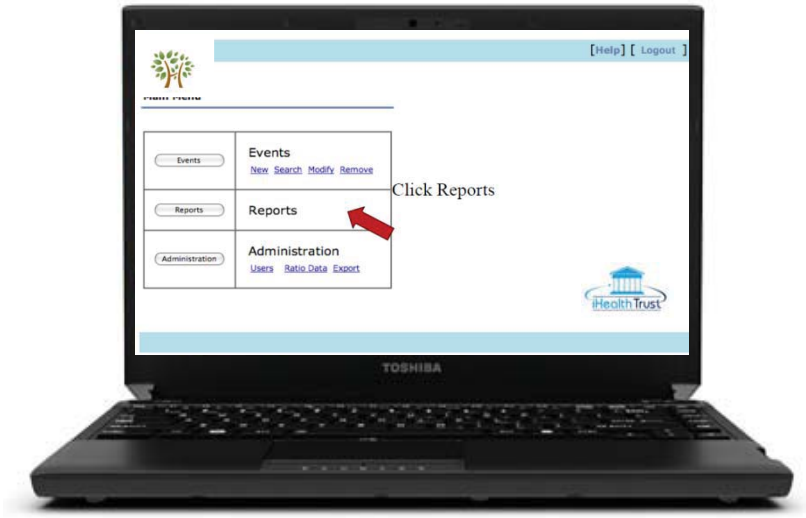


2. Future State Process

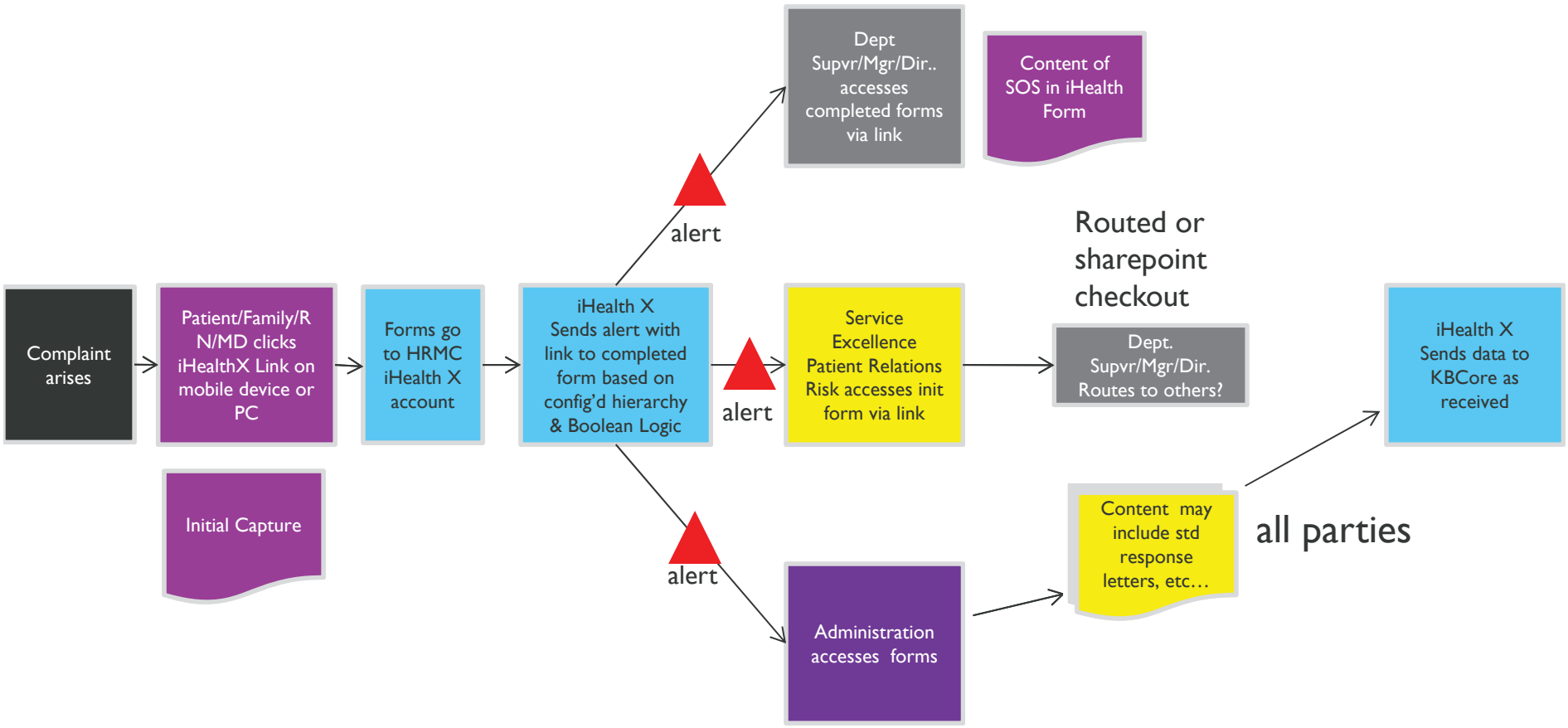
HRMC desktop Icon

Tell Me More

IHX Portal showing
- New entry
- Mgt Follow up
- Reporting etc



Flow Review Doc pg 1 of 2



Initial entry

Escalation notification

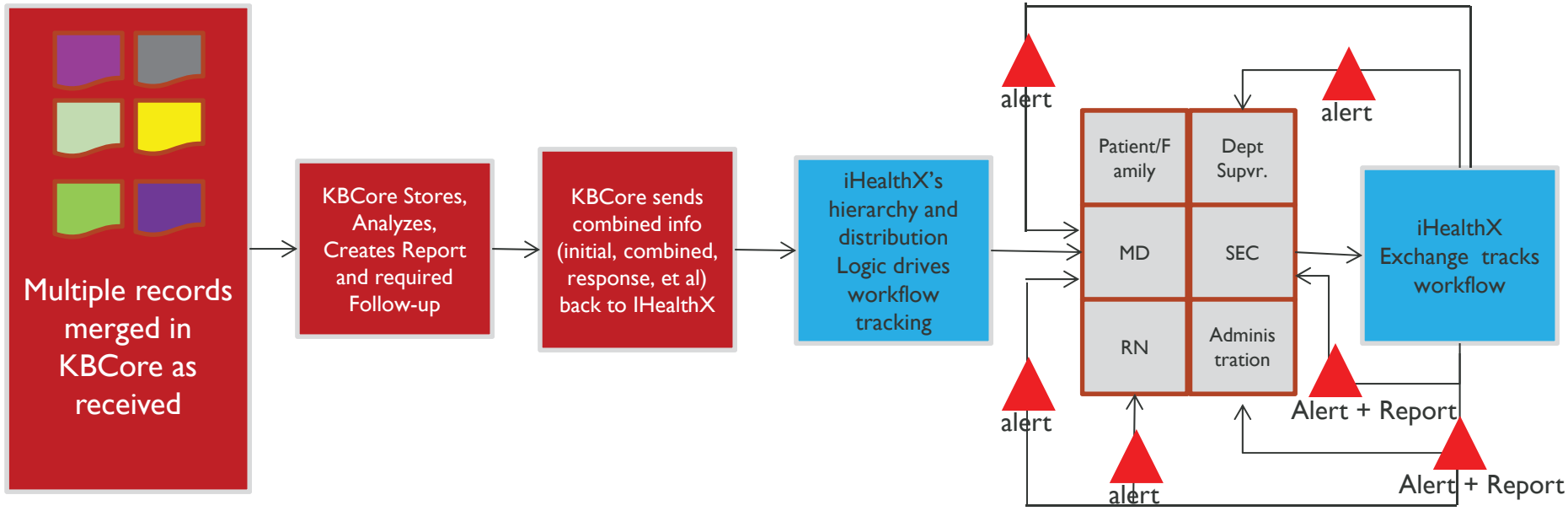
Review and Updating of records if req'd

|

If response is timely and effective…
follow concern protocol vs. grievance protocol

New Forms
Or Documentation added if Req'd

Flow Review Doc pg 2 of 2

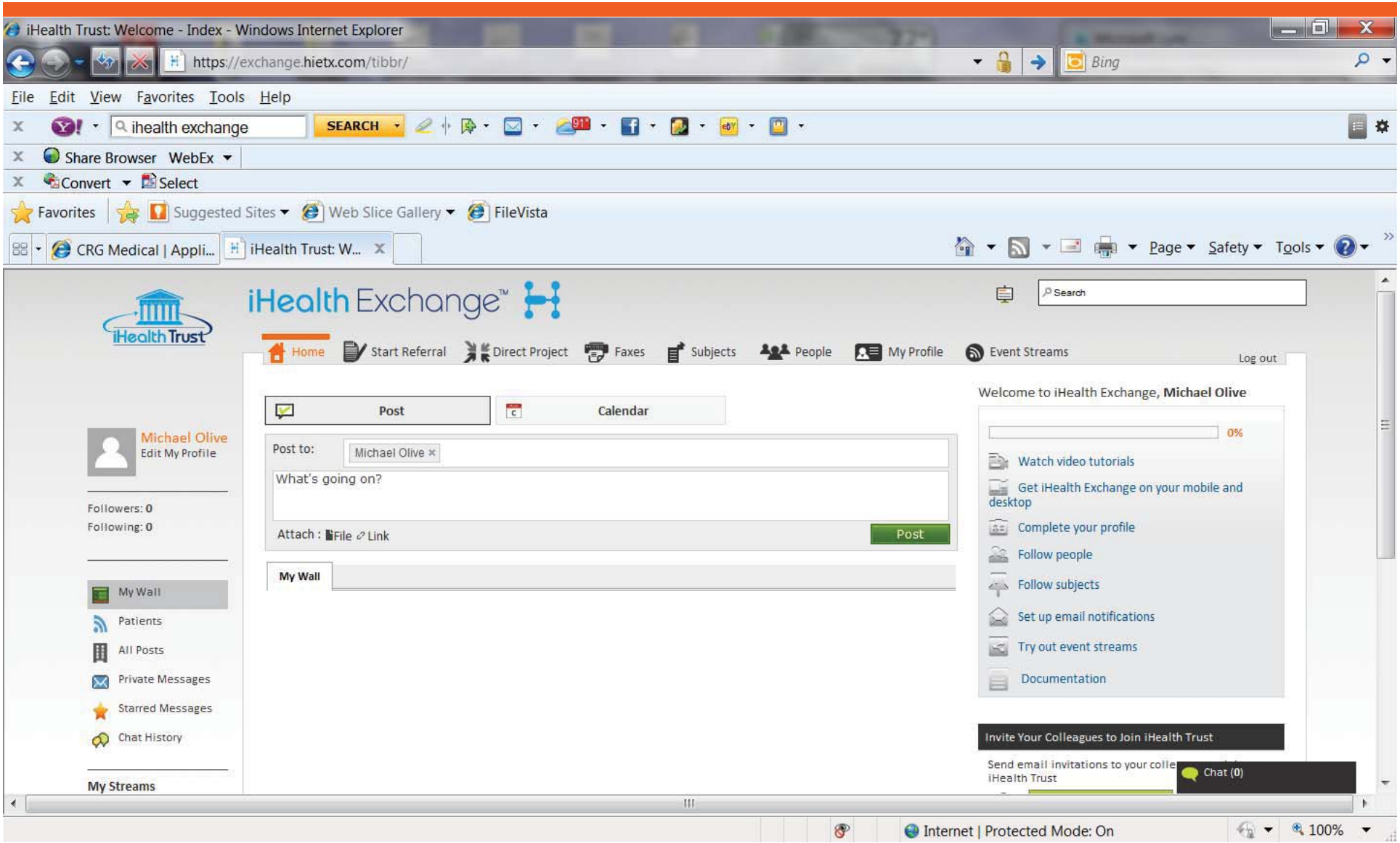


CRG **Medical**

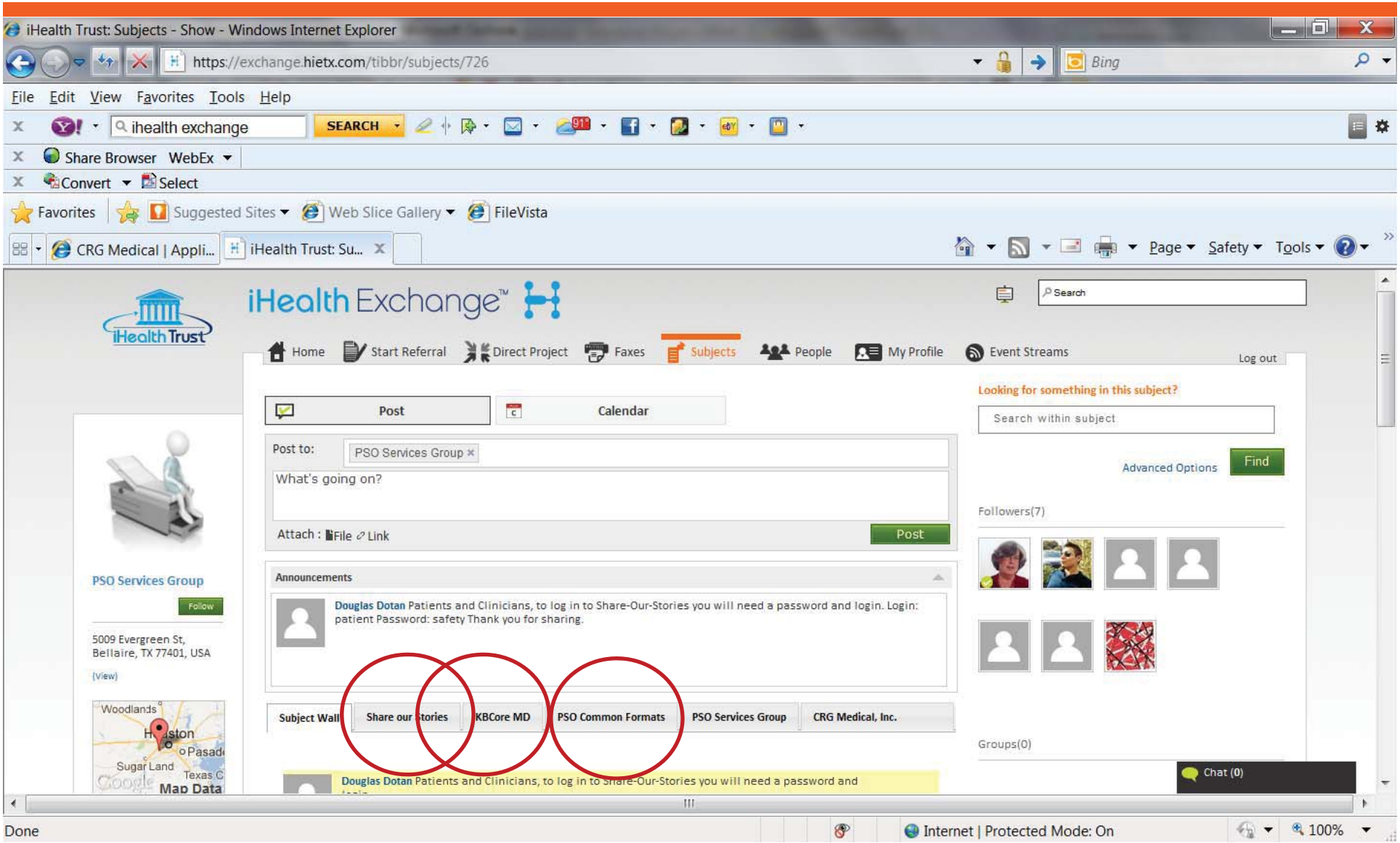
Web-based Healthcare Applications

How it looks in real life

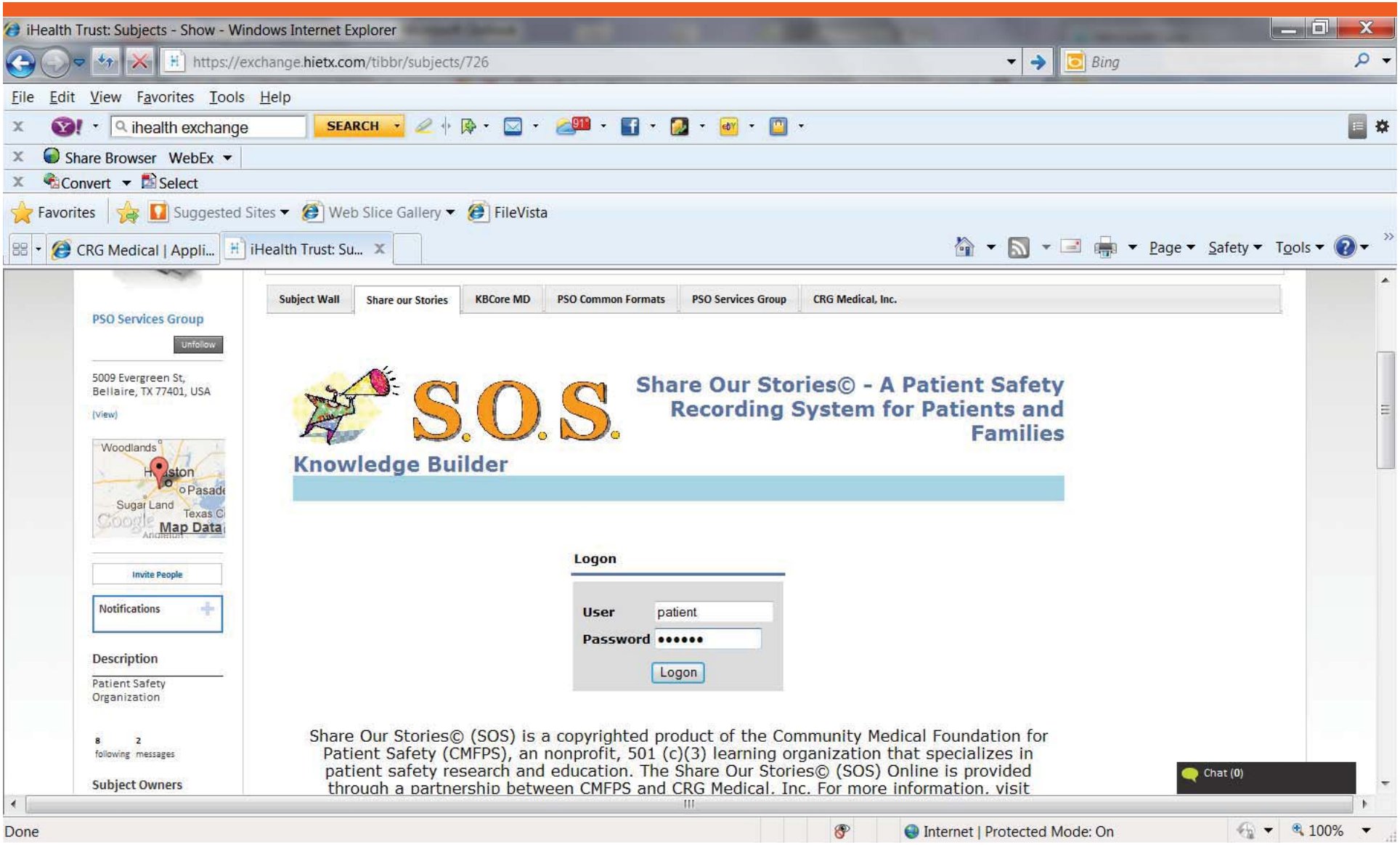
So you have either seen (RN/MD) or experienced something (PT/Fam) of concern, or have rec'd an alert (Supv/Mgr/Dir/CNO/SEC)…Log into your page from cell or laptop



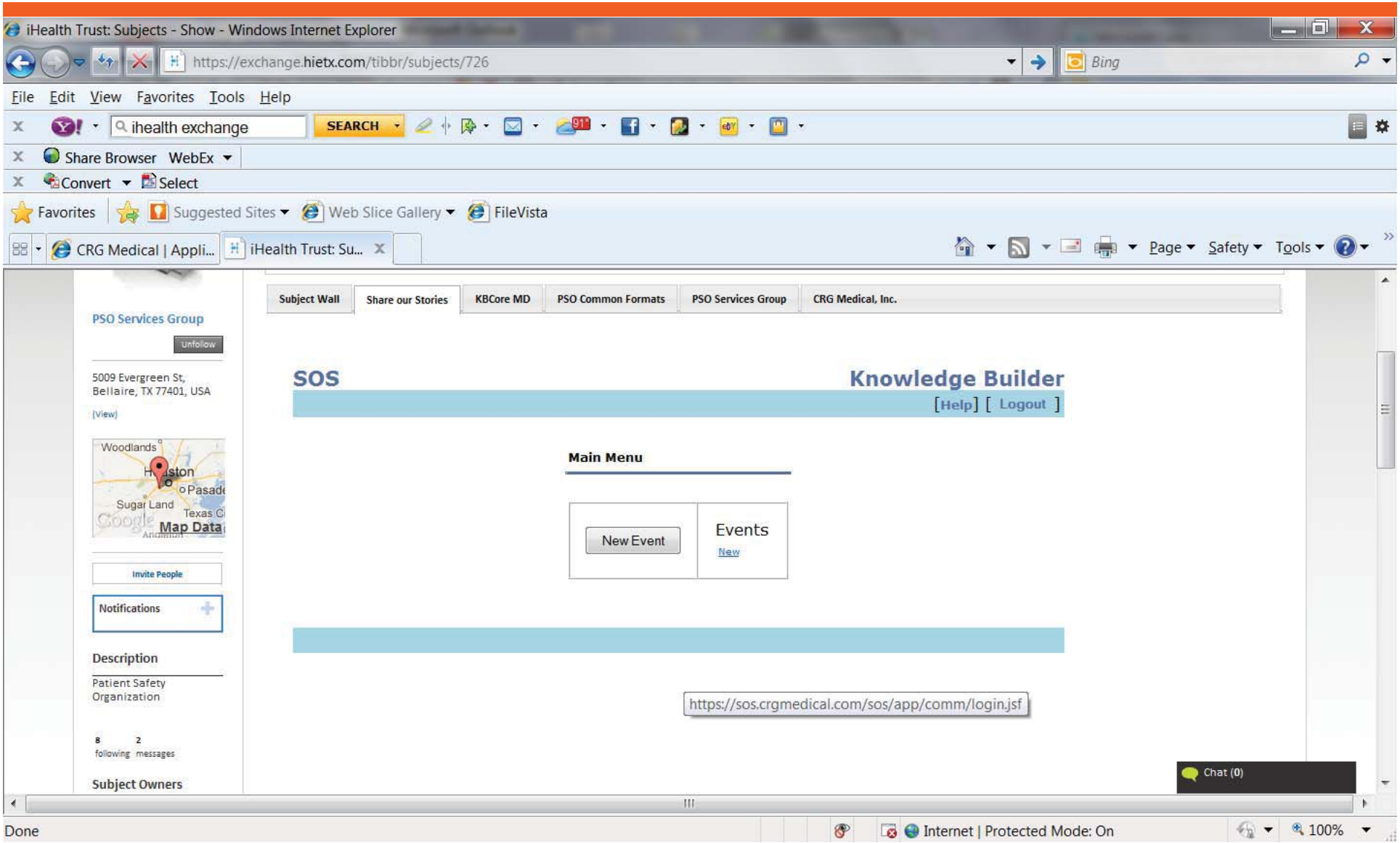
Select App Tab based on who you are…



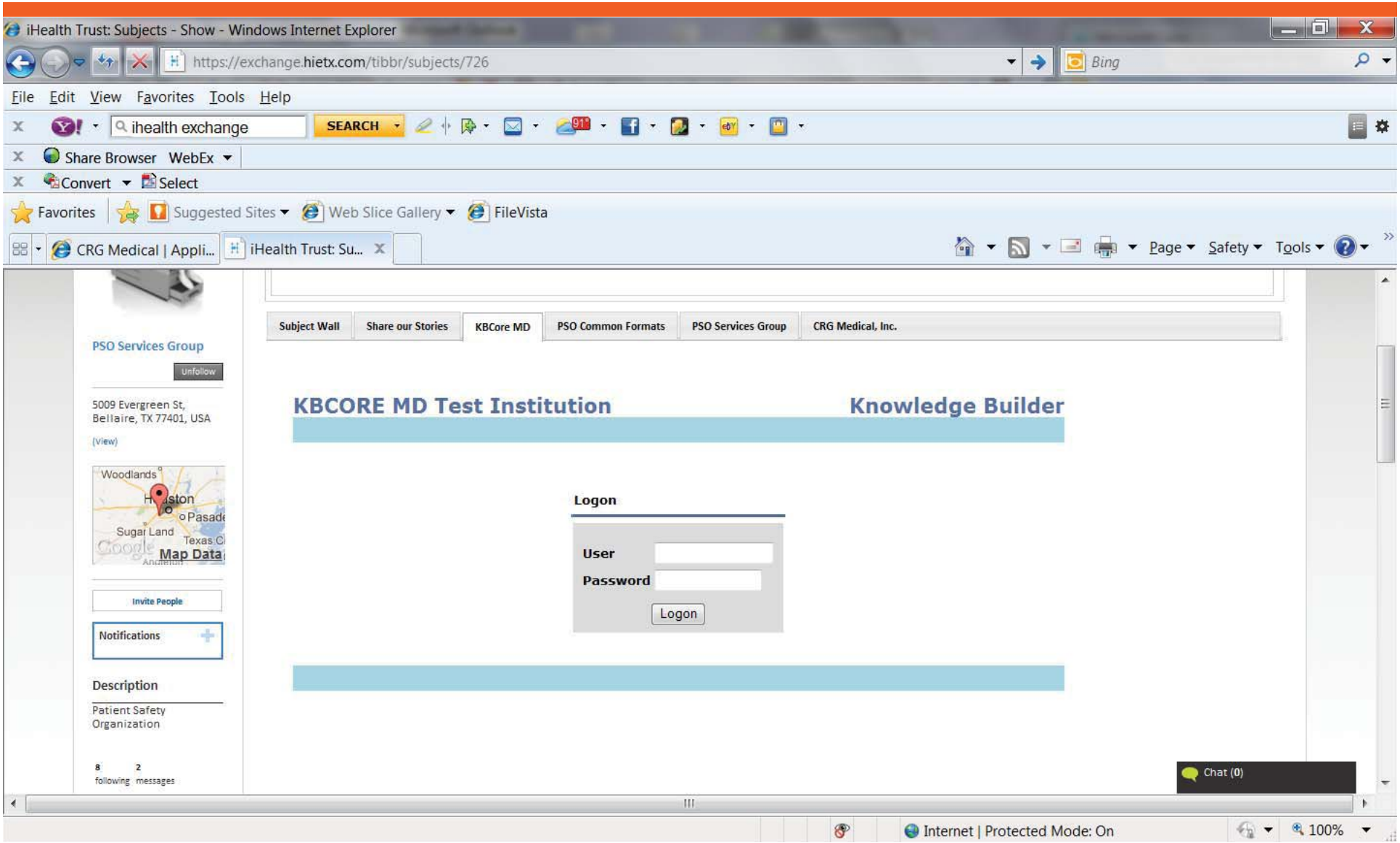
Patients and Family…Start App to begin the Info Capture



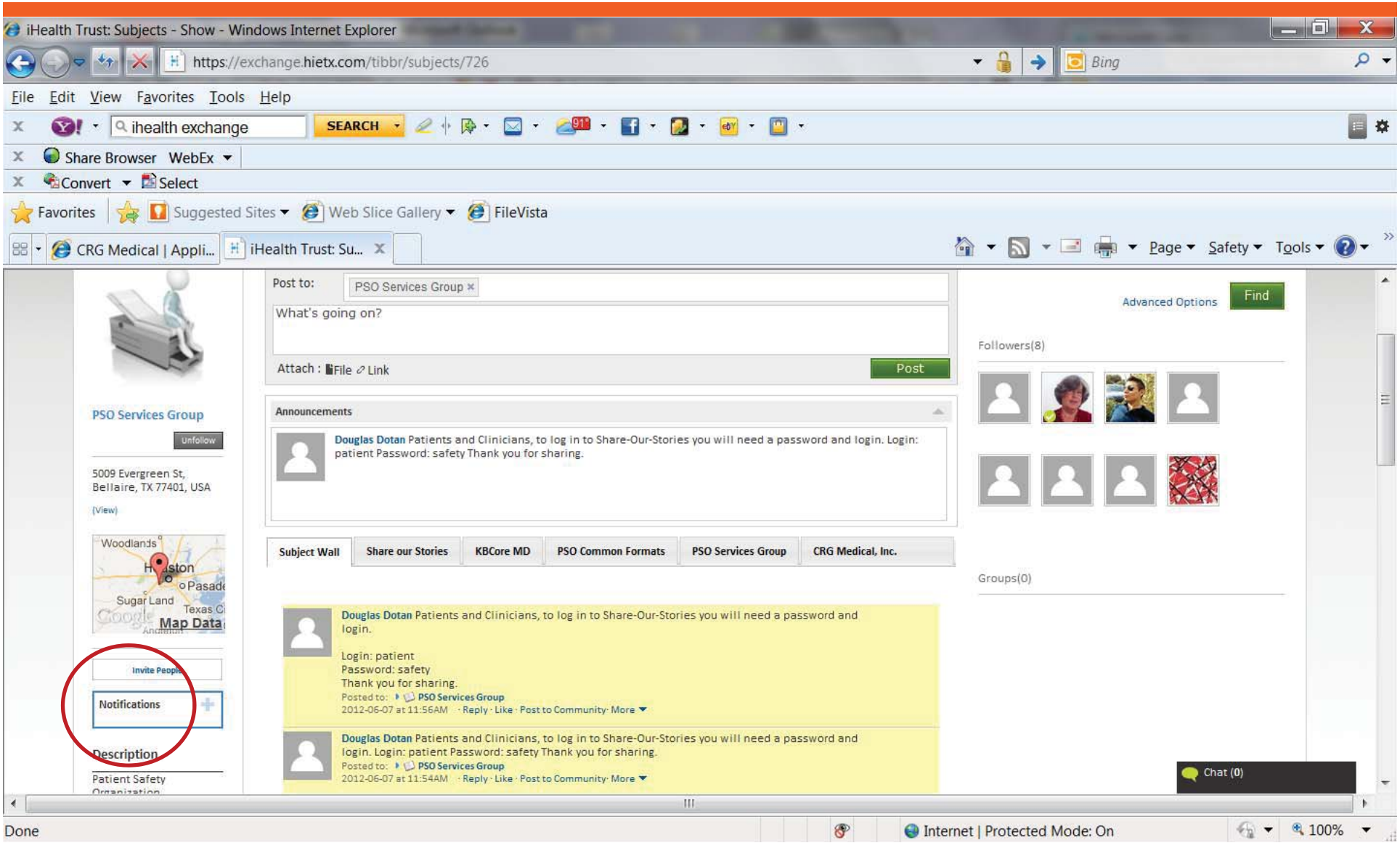
Patient entry start point

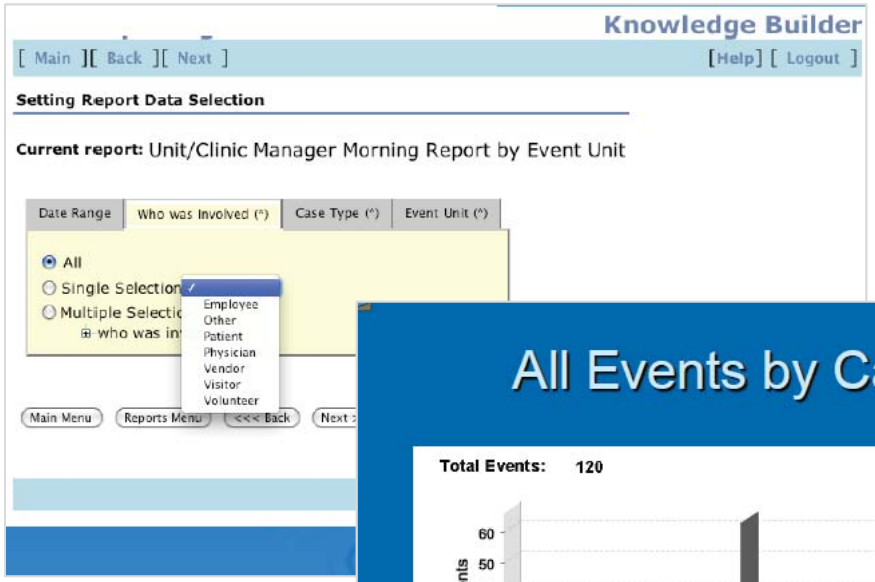


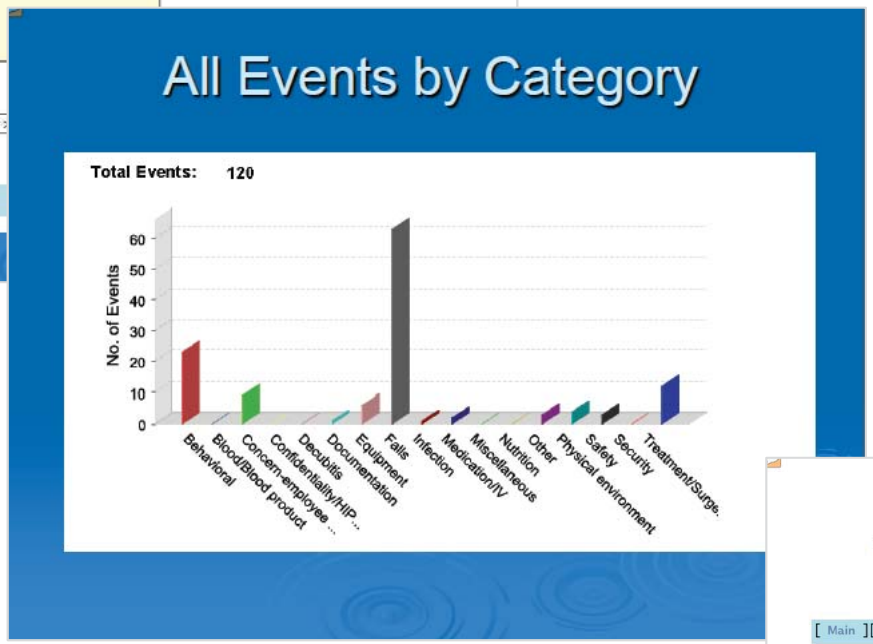
RN / MD entry start point



Pull up Alerts







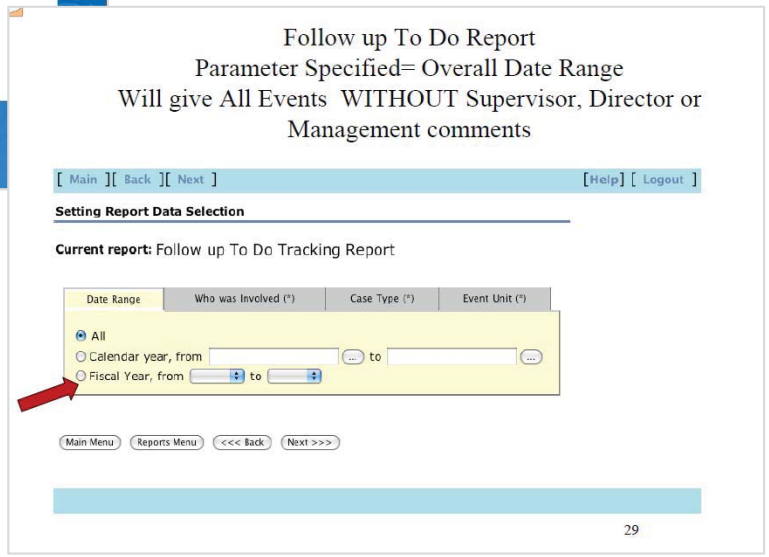
Reporting on single or multiple criteria

Analytics on events

What
Where
Why
How Often
Recurrence

Analytics on Hospital Response

Degree - Concern/Complaint/Grievance
Timeliness
Effectiveness
Compliance
Impact



Share Our Stories© (S.O.S.)

A Patient Safety Reporting System for anyone—patients, families and hospital staff experiencing a recent medical event that caused harm or could have caused harm or wanting to share a positive story or idea for safety.

You are not alone when you experience or observe a medical problem. You can share your story, learn from others' personal experiences, and save lives. Stories can be negative about a medical error or positive recommendation about a new idea, tip or suggestion to improve safety and quality of care.

The Share Our Stories© (SOS) created in 2006 is a new patient safety reporting system for patients, families and hospital staff. SOS is completely anonymous. It is administered by an independent nonprofit neutral party dedicated to patient safety. SOS reports will be collected, studied, and shared with others. All patients admitted to the hospital will receive a unique patient identification number and a password to access SOS. Patients are encouraged to use SOS to share their stories electronically on the hospital's computer system or approved handheld device. For more information about SOS, please contact your doctor, nurse or case manager

River Oaks Hospital
Patient Safety Committee
4200 Twelve Oaks Drive
Houston, TX 77027
713.964.8724

Share Our Stories© (S.O.S.)

A Patient Safety Recording System for patients, families, hospital staff, and volunteers who have had a recent medical experience that has caused harm or could have caused harm or anyone who wants to share a positive story about or idea or tip for safety. You are not alone when you experience or observe a medical problem. You can share your story, learn from others' personal experiences, and save lives. Stories can be negative about a medical error or positive about a new idea or suggestion to improve safety and quality of care.

SOS is completely anonymous. It is developed and administered by the independent nonprofit organization Community Medical Foundation for Patient Safety and used since 2006. You may go online* to share your story with the username and password at

https://sos.crgmedical.com/sos/app/comm/login.jsf.

Username: patient
Password: safety

It is important for everyone to share experiences about any problem, such as a medical error, so we all can learn from this experience and prevent future occurrences. Equally important are the stories with a good recommendation or tips to improve safety and quality of care. SOS reports will be collected, studied, and shared with others to improve best practices.

Community Medical Foundation for Patient Safety
6300 West Loop South, Suite 288
Bellaire, TX 77401
832.778.7777
mail@comofcom.com

*The online SOS Patient Safety Recording System is generously provided by our partner CRG Medical, Inc. (www.crgmedical.com).

WHY PEP- the Patient Experience Program?

Physician practices require positive risk management and quality assurance programs as well as complaint management systems for many reasons, including good patient/customer relationships; minimization of loss, be it time, money or reputation; and the benefit of not making mistakes, including the prevention of injury, the cost of re-work and employee morale. Physicians have long employed RM briefings by their insurance companies, and have developed policies and procedures for managing certain areas, such as HIPAA, billing and medical records. Yet, many physician offices do not have an easy electronic means for capturing information that could improve those programs and policies.

PEP, the Patient Experience Program.
In order to overcome this predicament we must first improve our understanding of these events. It is, therefore, crucial to improve all types of event reporting, especially by busy care providers. To do so, reporting must be:

- Easy and fast
- Confidential
- Provide a clear benefit to the reporter.

What do physicians and staff want to know? The short answer, how to make the right decisions at the right time in the right way for the right person…. and to know when those elements are NOT in place. There are three types of reports: first, any report from a patient or family member to a staff person. Secondly, a direct report form the patient and third an event or potential event reporting procedure.

PEP, the Patient Experience Program. is a unified set of modules for the collection and analysis of safety event reports:

Complaint/Grievance Module, used by facility staff
Event Reporting Module, used by staff to report events and near misses
SOS ,Share Our Stories, used by patients to report positive or negative experiences

PEP uses a web and mobile application for easy reporting and feedback and includes a health information exchange platform that enables secure communication between health professionals, and organizations. Staff access each module via an IHE page, from a desktop or mobile device, and progress quickly through the complaint and event modules. If wished, the additional followup Steps are accessed by an email link sent only to those with permissions to use the alert and routing system.

PEP was designed to
–Demonstrate how current process can be electronically automated

–Demonstrate potential enhancements to process and system logic that can be used to improve ease / effective capture, workflow tracking, alerts, transparency, reporting, accountability, consolidation of documentation/analysis and recurrence prevention.

Complaint and Grievance Reporting: the inpatient arena provides a model for complaint reporting to a staff member, distinguishing between complaints and grievances, including recognition of the failure to resolve a complaint within a reasonable time frame. Complaints include a letter indicating treatment was unsatisfactory resulting in too many office visits, letters re: rude staff, or the failure to recognize and act upon an abnormal lab finding resulting in progression of disease, and can escalate to filing with the TSBME. Timely documentation of complaints with follow-up at the proper level can minimize the number of complaints as well as their severity.

Event Reporting: … the opportunity for mis- and missed diagnosis looms large in the out patient setting even though it may occur infrequently. While small in number, sometimes the flow of care can go quite badly. Patients are lost to followup, xray and lab findings are missed, patients family members or visitors fall on the office. Insurance companies define what events must be reported, however, documenting near misses and hazardous situations allows analysis of what went right as well as what went wrong.

Health Information Exchange – Secure communication and professional social networking

KBCore has partnered with iHealth exchange, a healthcare communication platform which is endorsed, governed, and secured by the Texas Health Services Authority - iHealth Trust. Once a safety event is identified, KBCore uses the iHealth system to notify the relevant stakeholders and collect the necessary information from the reporter.

Apart from securing all the data collections in our system, iHealth exchange provides a safe environment where reporters, safety officers and other officials can exchange information regarding safety events. It is like a secure facebook for health professionals. A user can post a message on the wall asking their colleagues for advice, or use the Direct-project NWHIN email service to correspond with the safety officer or the PSO to provide additional details. These safe communication capabilities increase the sense of confidentiality and provide a utility from the system that is beyond reporting.

Reporting must be confidential – PEP provides an added level of confidentiality beyond the liability protection of the PSO. It addresses the reporters' fear of exposure to colleagues and superiors by allowing reporting under a group. Compared to the existing option of an anonymous report, group reporting conserves important information about the location of the event and properties of the reporter. In addition, by partnering with iHealth Exchange, an endorsed and supervised Health Information Exchange platform, we are able to provide secure communication capabilities and ensure data security will not be breached.

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Comments on Consumer Reporting System for Patient Safety
Date:	Tuesday, November 13, 2012 9:22:50 AM
Attachments:	image002.png CRSPS Comments_11_9_2012.pdf

From: Becky Miller [mailto:bmiller@mocps.org]
Sent: Friday, November 09, 2012 5:23 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Comments on Consumer Reporting System for Patient Safety

Please accept the attached comments per the Federal Register posting of September 10, 2012. Thank you.

Becky Miller, MHA, CPHQ, FACHE
EXECUTIVE DIRECTOR
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November 9, 2012

Doris Lefkowitz
Reports Clearance Officer
Agency for Healthcare Research and Quality
Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850

Re: Response to Federal Register Request for Comments on a Prototype Consumer Reporting System for Patient Safety Events

Dr. Ms. Lefkowitz:

Thank you for the opportunity to comment on the Monday, September 10, 2012 Federal Register notice pertaining to the Agency's Proposed Project, Prototype Consumer Reporting System for Patient Safety (CRSPS) Events.

We concur with the following issues that were raised in the Federal Register posting:

- consumers are in a position to view their own care and that of loved ones from a broad spectrum over the continuum of care not possible for individual providers
- information from consumers could be beneficial to better understanding of the breadth of medical mistakes and near misses that occur within healthcare delivery
- not all adverse medical events are reported through current systems
- there is no consistent system to obtain reports from patients and families across the nation
- any proposed consumer event reporting system should be thoroughly evaluated and tested, and include input from federally-designated Patient Safety Organizations (PSOs)
- the collection of information from consumers should be standardized and it is reasonable to utilize the AHRQ-developed Common Data Format that are currently utilized by PSOs

We submit the following questions and comments for consideration as the testing and research of a consumer event reporting system moves forward:

- We believe that providers will be aware of many of the issues reported through the proposed CRSPS, many designated as Patient Safety Work Product within the provider's Patient Safety Evaluation System, protected from disclosure by the Patient Safety and Quality Improvement Act of 2005 (Act). *How can discussions occur between the CRSPS staff and providers on event data and information that is PSWP within the provider's PSES without the provider violating the Act?*
- The CRSPS should support the continued improvement of the safety culture that encourages reporting of adverse events; if the system is perceived as punitive in any way

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or result in potential legal action or compliance or financial penalties, positive work over the recent decade to improve safety culture could be circumvented.

- We believe the estimate of patients who will give permission for CRSPS staff follow-up is underestimated. Most patients who report events do so to obtain follow-up and resolution; therefore much more than ten percent will likely permit CRSPS to follow-up. *What organization will provide the follow-up? Will the organization and its designated staff be authorized to have access to a providers' PSWP? CRSPS staff should have a strong skill set and understanding of provider and patient safety evaluation processes.*
- We believe the estimate of provider time required for CRSPS follow-up is underestimated. CRSPS events that the provider is not aware of will require a comprehensive review of documentation, interviews and following provider policy for event evaluation and reporting requiring much more than 20 minutes. Follow-up will also require providers to evaluate documentation and information as it pertains to their PSO reporting of PSWP and what can be discussed with CRSPS staff, likely requiring addition time and expense from legal consultation. *Consideration should also be given to how CRSPS reports will be evaluated to ensure only legitimate concerns are submitted for provider follow-up.*
- The CRSPS should not circumvent or duplicate provider efforts to comply with the CMS and Joint Commission requirements: CFR 482.13, CMS Conditions of Participation requires every hospital to have a grievance program for patients/family members to file complaints. The Joint Commission requires accredited providers to have a complaint process in place (RI.01.07.01).

Again, thank you for the opportunity to provide these comments and questions.

Sincerely,

Becky Miller

Becky Miller, MHA, CPHQ, FACHE
Executive Director

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Consumer comments on A prototype consumer reporting system for patient safety events
Date:	Tuesday, November 13, 2012 9:21:39 AM
Attachments:	Patient Reporting comments to AHRQ FINAL 11-9-12.docx

From: Lisa McGiffert [mailto:lmcgiffert@consumer.org]
Sent: Friday, November 09, 2012 6:57 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Consumer comments on A prototype consumer reporting system for patient safety events

Dear Doris Lefkowitz:

We appreciate the opportunity to respond to AHRQ's proposal to test a model for consumer reporting of medical errors through the creation of "A prototype consumer reporting system for patient safety events" as posted in the Federal Register (September 10, 2012, pp. 55475-55477).

As consumer advocates for safer health care (signatures below), we believe that gathering information from patients who have been harmed while receiving health care is a great idea - one that consumer advocates have suggested for years.

An estimated one in four patients is harmed when hospitalized – yet the oversight of medical harm is weak, underfunded and often hidden from public view. Our nation's response system to this leading cause of death in America fails patients every day through an unwillingness to approach this problem with urgency and accountability. The recent Hepatitis C and meningitis outbreaks are illustrations of a system clearly unable to respond adequately to protect patients.

Incidences of medical harm rarely are reported. A recent memorandum report by the Office of Inspector General, Department of HHS, found that in states that required reporting of certain medical errors, hospitals only reported one percent of these events. Most of the events that States required to be reported, but that hospitals did not report, were not identified by internal hospital incident reporting systems -- the staff did not view them as reportable events, even though some of them resulted in patient deaths. Although this is only one of many studies that have found significant underreporting of medical errors by hospitals, it highlights the need to bring patients' reports into the mix of identifying harm that is occurring in our health care system.

In general, we fully support the concept of consumer reporting of medical errors. We assume the results of this pilot will be used to design a system that could be used on a broader scale. In the future, patients should play a more meaningful role in reporting medical harm through a system that is sustainable and provides a benefit to those patients and the public.

We have reviewed the Federal Register notice and all of the accompanying attachments and have some concerns, comments and recommendations regarding the details of this demonstration project. Our three priority concerns are the lack of public transparency, the lack of a clear goal to benefit patients and diversion of patients from filing complaints with agencies that have statutory oversight of hospitals, clinics and physicians.

Public transparency. We believe public reporting is an essential component to improve patient safety and an essential part of that is to connect the harm with the providers. Many of us worked to establish hospital infection reporting systems in our states and are keenly aware of the impact that publishing infection rates has had in motivating hospitals to improve patient safety, reducing infections and saving lives.

While this project plans to only produce aggregated reports, our review of all of the accompanying documents finds no reference to providing those reports to the patients who helped to create them or to the public. Instead, the aggregated reports are to be given to "doctors, hospitals, and pharmacists so they can make health care safer." The public should also have access to these reports. Further, the project should build in a process by which all patients who submit reports about their personal experiences will be notified when the aggregate report is completed and provided with directions on how to access that report.

Goals of the system: The three stated goals of this demonstration project are:

1. To develop and design a prototype system to collect information about patient safety events.
2. To develop and test Web and telephone modes of a prototype questionnaire.
3. To develop and test protocols for a follow-up survey of health care providers.

We are concerned that there is no goal to follow up with the patients. Clearly this project recognizes the importance of collecting information from patients who have been harmed, but in reviewing the details, there is no recognition of patients' rights to know what happened to them and why. This is fundamentally what most harmed patients want to find out. The proposal estimates that only a small number of patients will agree to have their information shared with the providers involved. These patients are taking some risks in doing so and deserve to be fully included in the "experiment" of using their information to make their providers practice safer health care. The patients should be informed regarding the providers' responses and regarding any positive outcomes that resulted from their disclosure (e.g., the provider changed a particular practice to ensure similar errors don't happen in the future).

We recommend adding a fourth goal: To develop and test protocols for providing follow up to patients who have filed reports.

Diverting medical error reports from regulatory agencies. If our system of oversight really worked, patients would be well informed about where to file reports when they have witnessed or experienced safety problems, the regulatory agency would investigate the report and some kind of corrective action would occur. Instead, the health care system's response to medical errors has condoned secrecy, avoided addressing underlying safety problems and left patients and their families with terrible losses and huge medical bills. While we acknowledge that our health care oversight systems are lacking, we believe more attention should be directed at improving them.

What we really need is a public awareness campaign to inform harmed patients about how to file complaints against hospitals and doctors. A 2011 Consumers Union national randomized poll found that only one-quarter of respondents said they would know where to file a complaint about a medical error they experienced at a hospital.

Creating a completely separate consumer reporting system – one that promises no tangible

accountability or help to consumers of health care – might not be the most effective way to engage patients in improving care. Every state and federal programs like Medicare have systems in place to collect and investigate consumer complaints. Our concern is that people participating in the pilot project will be misled to believe this survey is an official reporting process that will lead to some kind of resolution to the incidents of medical harm. Harmed patients need their problems addressed -- analyzing their reports privately with their providers and aggregately reporting the information to other providers won't help them and might not effectively identify the providers with the biggest problems.

To address this issue, we recommend that the project proactively inform and guide patients to the appropriate agencies that license hospitals, doctors, etc., for reporting what happened to them. This would make the project's role perfectly clear, while bolstering our oversight system with information it needs to identify providers who may not be doing enough to ensure that patients are safe.

Other comments:

- The method of outreach for testing this prototype at a local level appears to be a good plan. Creating a community-based marketing campaign and handing the flyer (which is direct and understandable) to patients at several points in their discharge and follow up process provide the repetition that might encourage more of them to participate. We are concerned though, how this approach will translate into a national system. While it may work at a local level, with full agreement with the hospitals to help with this outreach, it will be a significant challenge to implement on a broader scale.

- The project should recognize that many of these patients are still under the care of the providers who may have caused them harm and speaking up could result in retaliation. We didn't see any discussion about how to protect against or respond to such actions. ***We recommend that the project develop a written strategy for protecting against retaliatory actions in a way that makes the patient the priority and not the provider and for responding to such acts when they occur.***

- Creating two new euphemisms for medical harm –"health care safety concern" and "negative effect" – is unnecessarily confusing. Neither terms are widely used and may have little meaning to the general public or health care providers. Further, we consider these to be "soft" terms and paired with some of the other descriptive text in the accompanying documents, they tend to minimize the impact or experience of medical errors. For example: "A safety concern is anything that happens with your doctor or hospital or pharmacy that worries you because you think it isn't safe. It does not have to be something that resulted in harm. Maybe nothing bad happened but there was ***almost*** a mistake—we call this a 'near miss.'" Seeking information from someone whose child just died by asking if they were "concerned" or "worried" is inappropriate. Is the project seeking people's "safety concerns" or is it trying to find out about harm and injury that patients experience in the process of receiving health care? Too often the language used in the documents that patients will see fails to appropriately reflect the seriousness of these experiences. In 2011 Consumers Union

conducted a survey on patient safety, which asked among other things for consumers to choose the terms that best describe preventable problems that occur when receiving medical care. Only three terms were singled out by more than 1 in 10 consumers: Medical error, Medical mistake and Treatment error. ***We recommend that the project use one common term consistently rather than make up completely new terms that are not commonly used.***

- One of the goals of the project appears to be to provide real life local examples of harm to providers rather than attempt to accumulate some kind of record of the harm that is happening in a particular town. Clearly most of the patient reports will not be identifiable or shared with the providers involved with the error, rather they will be incorporated into aggregate reports that are not made public. We believe there are much more efficient, less costly ways to provide these types of anonymous examples of medical harm to providers.

- Most of the descriptive text in all of the attachments (such as the scripts for phone calls, FAQs, and introductory explanations) highlights that specific patient information will not be offered to the doctor or hospital. This claim is made repeatedly throughout the documents, for example: "We will only tell doctors, hospitals, and pharmacists a compilation of what we learn; no individual reports are shared. We hope they will make changes and that health care will be safer;" "I give my permission to the CRSPS team to use my information as long as they do not share my name and other identifying information." The project's intention to ask patients for permission to share their identifiable information with their providers only appears in a few places: in the middle of the survey and in a statement in Attachment A (website intro): "I understand my individual answers to the survey questions are strictly confidential and will not be seen by anyone outside the CRSPS team, unless during the reporting process I agree to allow the CRSPS team to share this information." The FAQ document mentions nothing about giving the patients specific information to the providers involved in their care. It thoroughly covers the issues of confidentiality of all of the information provided but fails to discuss the option to share identifiable information. We believe people will be less likely to trust the project if, after repeatedly reading about how their information will not be shared, they are surprised with asking them to share their personal information to with the providers who caused the harm. ***We recommend that language similar to that cited above from Attachment A be incorporated into other statements about confidentiality.***

- We have some concerns with non-government entities that are relatively unknown to consumers as the collectors and the repository for a consumer reporting system for errors. We think most people would be more comfortable and would report more readily to a government agency than they would to an entity they've never heard of. This should be carefully considered when a broader national system is created. Government agencies are not perfect and may be subject to political pressure, but in the long run we think people would trust that AHRQ, for example, would be more likely to be independent, not be influenced by industry and act in the public interest than employees of a group in the private sector.

Specific Feedback about the web survey tool (attachment B): While we are not providing an exhaustive critique of the survey tool, we have a few comments that we think should be addressed:

- Questions 3.7 and its follow up are too simplistic. 3.7 asks: "Did a doctor, nurse, or other health care provider make any special effort to help the patient handle the mistake? " If the patient answers "yes," the follow up question (3.7.1) asks: Did it help? Yes/no/don't know. We recommend adding a box to this question (or more choices) so the patient can provide more information as to the kind of "help" that was offered and why it did or didn't help. Questions 4.8 and 4.81 repeat these questions.

- Questions 3.6 and 4.7 ask: "How did the patient find out that the mistake happened?" but do not offer limited choices regarding the outcome of the mistake. For example, adding an option to indicate that the patient "found out" about the mistake because the patient died or was disabled or harmed. Instead the responses given in the current survey are more in line with minor concerns, such as asking when and how someone "noticed" the mistake. While we like that a text box is included to enable the consumer to give more information, we think it would help to add at least one more choice indicating that they became aware of the mistake because of death or incapacitation – omitting the recognition that people often find out about mistakes when they become seriously ill seems to be an obvious oversight.

We look forward to seeing the results of this experiment, but believe the optimal direction for national patient reporting is through a system similar to that used to gather HCAHPS surveys. It would not depend on volunteers and the results would be public with the identity of the hospital or physician included. Ultimately, to eliminate medical harm, we need a publicly accessible system that integrates all sources of information being collected about health care safety to reveal a full picture of a provider's safety record – that would include patient reports, reports by providers on outcome measures (e.g., health care-acquired infections, hospital acquired conditions), licensing agency records and inspections, accreditation reports, and medical malpractice settlements. Assessing patient safety in silos allows providers with the biggest problems that need the most help for improvement and accountability to go undetected.

Sincerely,

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When he makes a mistake, he realizes it. Having realized it, he admits it. Having admitted it, he corrects it. --- Tao te Ching, Ch 61

Doris.lefkowitz@AHRQ.hhs.gov

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An estimated one in four patients is harmed when hospitalized – yet the oversight of medical harm is weak, underfunded and often hidden from public view. Our nation's response system to this leading cause of death in America fails patients every day through an unwillingness to approach this problem with urgency and accountability. The recent Hepatitis C and meningitis outbreaks are illustrations of a system clearly unable to respond adequately to protect patients.

Incidences of medical harm rarely are reported. A recent memorandum report by the Office of Inspector General, Department of HHS, found that in states that required reporting of certain medical errors, hospitals only reported one percent of these events. Most of the events that States required to be reported, but that hospitals did not report, were not identified by internal hospital incident reporting systems -- the staff did not view them as reportable events, even though some of them resulted in patient deaths. Although this is only one of many studies that have found significant underreporting of medical errors by hospitals, it highlights the need to bring patients' reports into the mix of identifying harm that is occurring in our health care system.

In general, we fully support the concept of consumer reporting of medical errors. We assume the results of this pilot will be used to design a system that could be used on a broader scale. In the future, patients should play a more meaningful role in reporting medical harm through a system that is sustainable and provides a benefit to those patients and the public.

We have reviewed the Federal Register notice and all of the accompanying attachments and have some concerns, comments and recommendations regarding the details of this demonstration project. Our three priority concerns are the lack of public transparency, the lack of a clear goal to benefit patients and diversion of patients from filing complaints with agencies that have statutory oversight of hospitals, clinics and physicians.

Public transparency. We believe public reporting is an essential component to improve patient safety and an essential part of that is to connect the harm with the providers. Many of us worked to establish hospital infection reporting systems in our states and are keenly aware of the impact that publishing infection rates has had in motivating hospitals to improve patient safety, reducing infections and saving lives.

While this project plans to only produce aggregated reports, our review of all of the accompanying documents finds no reference to providing those reports to the patients who helped to create them or to the public. Instead, the aggregated reports are to be given to "doctors, hospitals, and pharmacists so they can make health care safer." The public should also have access to these reports. Further, the project should build in a process by which all patients who submit reports about their personal experiences will be notified when the aggregate report is completed and provided with directions on how to access that report.

Goals of the system: The three stated goals of this demonstration project are:

1. To develop and design a prototype system to collect information about patient safety events.
2. To develop and test Web and telephone modes of a prototype questionnaire.
3. To develop and test protocols for a follow-up survey of health care providers.

We are concerned that there is no goal to follow up with the patients. Clearly this project recognizes the importance of collecting information from patients who have been harmed, but in reviewing the details, there is no recognition of patients' rights to know what happened to them and why. This is fundamentally what most harmed patients want to find out. The proposal estimates that only a small number of patients will agree to have their information shared with the providers involved. These patients are taking some risks in doing so and deserve to be fully included in the "experiment" of using their information to make their providers practice safer health care. The patients should be informed regarding the providers' responses and regarding any positive outcomes that resulted from their disclosure (e.g., the provider changed a particular practice to ensure similar errors don't happen in the future).

We recommend adding a fourth goal: To develop and test protocols for providing follow up to patients who have filed reports.

Diverting medical error reports from regulatory agencies. If our system of oversight really worked, patients would be well informed about where to file reports when they have witnessed or experienced safety problems, the regulatory agency would investigate the report and some kind of corrective action would occur. Instead, the health care system's response to medical errors has condoned secrecy, avoided addressing underlying safety problems and left patients and their families with terrible losses and huge medical bills. While we acknowledge that our health care oversight systems are lacking, we believe more attention should be directed at improving them.

What we really need is a public awareness campaign to inform harmed patients about how to file complaints against hospitals and doctors. A 2011 Consumers Union national randomized poll found that only one-quarter of respondents said they would know where to file a complaint about a medical error they experienced at a hospital.

Creating a completely separate consumer reporting system – one that promises no tangible accountability or help to consumers of health care – might not be the most effective way to engage patients in improving care. Every state and federal programs like Medicare have systems in place to collect and investigate consumer complaints. Our

concern is that people participating in the pilot project will be misled to believe this survey is an official reporting process that will lead to some kind of resolution to the incidents of medical harm. Harmed patients need their problems addressed -- analyzing their reports privately with their providers and aggregately reporting the information to other providers won't help them and might not effectively identify the providers with the biggest problems.

To address this issue, we recommend that the project proactively inform and guide patients to the appropriate agencies that license hospitals, doctors, etc., for reporting what happened to them. This would make the project's role perfectly clear, while bolstering our oversight system with information it needs to identify providers who may not be doing enough to ensure that patients are safe.

Other comments:

- The method of outreach for testing this prototype at a local level appears to be a good plan. Creating a community-based marketing campaign and handing the flyer (which is direct and understandable) to patients at several points in their discharge and follow up process provide the repetition that might encourage more of them to participate. We are concerned though, how this approach will translate into a national system. While it may work at a local level, with full agreement with the hospitals to help with this outreach, it will be a significant challenge to implement on a broader scale.

- The project should recognize that many of these patients are still under the care of the providers who may have caused them harm and speaking up could result in retaliation. We didn't see any discussion about how to protect against or respond to such actions. ***We recommend that the project develop a written strategy for protecting against retaliatory actions in a way that makes the patient the priority and not the provider and for responding to such acts when they occur.***

- Creating two new euphemisms for medical harm –"health care safety concern" and "negative effect" – is unnecessarily confusing. Neither terms are widely used and may have little meaning to the general public or health care providers. Further, we consider these to be "soft" terms and paired with some of the other descriptive text in the accompanying documents, they tend to minimize the impact or experience of medical errors. For example: "A safety concern is anything that happens with your doctor or hospital or pharmacy that worries you because you think it isn't safe. It does not have to be something that resulted in harm. Maybe nothing bad happened but there was *almost* a mistake—we call this a 'near miss.'" Seeking information from someone whose child just died by asking if they were "concerned" or "worried" is inappropriate. Is the project seeking people's "safety concerns" or is it trying to find out about harm and injury that patients experience in the process of receiving health care? Too often the language used in the documents that patients will see fails to appropriately reflect the seriousness of these experiences. In 2011 Consumers Union conducted a survey on patient safety, which asked among other things for consumers to choose the terms that best describe preventable problems that occur when receiving medical care. Only three terms were singled out by more

than 1 in 10 consumers: Medical error, Medical mistake and Treatment error. ***We recommend that the project use one common term consistently rather than make up completely new terms that are not commonly used.***

- One of the goals of the project appears to be to provide real life local examples of harm to providers rather than attempt to accumulate some kind of record of the harm that is happening in a particular town. Clearly most of the patient reports will not be identifiable or shared with the providers involved with the error, rather they will be incorporated into aggregate reports that are not made public. We believe there are much more efficient, less costly ways to provide these types of anonymous examples of medical harm to providers.

- Most of the descriptive text in all of the attachments (such as the scripts for phone calls, FAQs, and introductory explanations) highlights that specific patient information will not be offered to the doctor or hospital. This claim is made repeatedly throughout the documents, for example: "We will only tell doctors, hospitals, and pharmacists a compilation of what we learn; no individual reports are shared. We hope they will make changes and that health care will be safer;" "I give my permission to the CRSPS team to use my information as long as they do not share my name and other identifying information." The project's intention to ask patients for permission to share their identifiable information with their providers only appears in a few places: in the middle of the survey and in a statement in Attachment A (website intro): "I understand my individual answers to the survey questions are strictly confidential and will not be seen by anyone outside the CRSPS team, unless during the reporting process I agree to allow the CRSPS team to share this information." The FAQ document mentions nothing about giving the patients specific information to the providers involved in their care. It thoroughly covers the issues of confidentiality of all of the information provided but fails to discuss the option to share identifiable information. We believe people will be less likely to trust the project if, after repeatedly reading about how their information will not be shared, they are surprised with asking them to share their personal information to with the providers who caused the harm. ***We recommend that language similar to that cited above from Attachment A be incorporated into other statements about confidentiality.***

- We have some concerns with non-government entities that are relatively unknown to consumers as the collectors and the repository for a consumer reporting system for errors. We think most people would be more comfortable and would report more readily to a government agency than they would to an entity they've never heard of. This should be carefully considered when a broader national system is created. Government agencies are not perfect and may be subject to political pressure, but in the long run we think people would trust that AHRQ, for example, would be more likely to be independent, not be influenced by industry and act in the public interest than employees of a group in the private sector.

Specific Feedback about the web survey tool (attachment B): While we are not providing an exhaustive critique of the survey tool, we have a few comments that we think should be addressed:

- Questions 3.7 and its follow up are too simplistic. 3.7 asks: “Did a doctor, nurse, or other health care provider make any special effort to help the patient handle the mistake?” If the patient answers “yes,” the follow up question (3.7.1) asks: Did it help? Yes/no/don't know. We recommend adding a box to this question (or more choices) so the patient can provide more information as to the kind of “help” that was offered and why it did or didn’t help. Questions 4.8 and 4.81 repeat these questions.
- Questions 3.6 and 4.7 ask: “How did the patient find out that the mistake happened?” but do not offer limited choices regarding the outcome of the mistake. For example, adding an option to indicate that the patient “found out” about the mistake because the patient died or was disabled or harmed. Instead the responses given in the current survey are more in line with minor concerns, such as asking when and how someone “noticed” the mistake. While we like that a text box is included to enable the consumer to give more information, we think it would help to add at least one more choice indicating that they became aware of the mistake because of death or incapacitation – omitting the recognition that people often find out about mistakes when they become seriously ill seems to be an obvious oversight.

We look forward to seeing the results of this experiment, but believe the optimal direction for national patient reporting is through a system similar to that used to gather HCAHPS surveys. It would not depend on volunteers and the results would be public with the identity of the hospital or physician included. Ultimately, to eliminate medical harm, we need a publicly accessible system that integrates all sources of information being collected about health care safety to reveal a full picture of a provider’s safety record – that would include patient reports, reports by providers on outcome measures (e.g., health care-acquired infections, hospital acquired conditions), licensing agency records and inspections, accreditation reports, and medical malpractice settlements. Assessing patient safety in silos allows providers with the biggest problems that need the most help for improvement and accountability to go undetected.

Sincerely,

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From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Written Comments--Prototype Consumer Reporting System for Patient Safety Events (CRSPS)
Date:	Tuesday, November 13, 2012 9:19:36 AM

From: Lucy Savitz [mailto:Lucy.Savitz@imail.org]
Sent: Friday, November 09, 2012 7:13 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Written Comments--Prototype Consumer Reporting System for Patient Safety Events (CRSPS)

I am writing on behalf of:
The Intermountain-led Hospital Engagement Network and
The University of Utah Center for Clinical and Translational Science, Community Engagement Core
In response to the call for public comment on CRSPS.

Overall, we are in support of this important tool to give voice to patients/families/caregivers in identifying and promoting patient safety.
We believe that the system should provide sufficient detail to delivery systems that would afford linkages to:

1. Link with clinical data to verify that an event occurred;
2. determine the type of event and a "score" (that currently does not exist) related to the preventability and seriousness of the incident; and
3. Design national reporting that would stratify the types of events reported with specific notations on those that had been vs. those that had not been verified.

Much of hospital resources are devoted to sentinel events and such a system would help elucidate patterns in near misses and other preventable events to the benefit of overall patient safety.

Thank you for this opportunity to comment.

Lucy Savitz

Lucy A. Savitz, Ph.D., MBA
Project Director, Intermountain-led Hospital Engagement Network
Director, University of Utah CCTS Community Engagement Core
801-442-3049

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Comments, AHRQ"s proposed ""A Prototype Consumer Reporting System for Patient Safety Events, "" Federal Register /Vol. 77, No. 175 /Monday, September 10, 2012 /Notices, No Docket No. Provided.)
Date:	Friday, November 09, 2012 10:44:26 AM
Attachments:	ADVERSE.EVENTS.PATIENT.REPORTING.AHRQ.COMMENTS.11.9.2012.docx

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From: Barry Furrow [mailto:barry_furrow@hotmail.com]
Sent: Friday, November 09, 2012 10:43 AM
To: Lefkowitz, Doris C. (AHRQ)
Cc: Barry Furrow
Subject: RE: Comments, AHRQ's proposed "A Prototype Consumer Reporting System for Patient Safety Events, " Federal Register /Vol. 77, No. 175 /Monday, September 10, 2012 /Notices, No Docket No. Provided.)

Dear Ms. Lefkowitz:

I have resent our comments, this time with a full heading in the Subject box just in case your spam filter has screened out my first submission.

Thank you.

Sincerely yours,

Barry R. Furrow
Professor of Law
Director, Health Law Program

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From: barry_furrow@hotmail.com
To: doris.lefkowitz@ahrq.hhs.gov
CC: barry_furrow@hotmail.com
Subject:
Date: Fri, 9 Nov 2012 10:38:58 -0500

Dear Ms. Lefkowitz:

You have requested comments on AHRQ's proposed information collection project: ''A Prototype Consumer Reporting System for Patient Safety Events, '' **Federal Register** /Vol. 77, No. 175 /Monday, September 10, 2012 /Notices, *No Docket No. Provided*.)

We have attached our Comments to this email, in response to your request for comments.

If you have any questions, please feel free to email or call me, as the primary contact for

these comments.

Thank you.

Sincerely yours.

Barry R. Furrow
Professor of Law
Director, Health Law Program

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EARLE MACK SCHOOL OF LAW
Drexel University

BARRY FURROW
PROFESSOR OF LAW
DIRECTOR, THE HEALTH LAW PROGRAM

November 9, 2012

Doris Lefkowitz, Reports Clearance Officer
Agency for Healthcare Research and Quality

Dear Ms. Lefkowitz:

You have requested comments on AHRQ's proposed information collection project: ''A Prototype Consumer Reporting System for Patient Safety Events, '' **Federal Register** /Vol. 77, No. 175 /Monday, September 10, 2012 /Notices, *No Docket No. Provided*.) You describe the proposed reporting system as having the goals of developing and designing a prototype system to collect information about patient safety events; Web and telephone modes of a prototype questionnaire; and protocols for a follow-up survey of health care providers.

The proposed method of collection includes a safety event intake form and follow up. The form asks about a medical error or mistake, harm or injury as well as near misses, with voluntary reporting by patients, family members and other caregivers through a Web site or by telephone. You propose a range of questions: "what happened, details of the event, when, where, whether there was harm, the type of harm, contributing factors, disclosure, and whether the patient reported the event and to whom." The willingness of reporters to answer follow-up questions by CRSPS staff is also asked. This follow-up by phone will elicit further information and annotate the report.

For consenting consumers, you will establish a cross check system, sharing the consumer reports with patient safety officers at health care institutions that maintain adverse event reporting systems. The purpose of this is to determine if the consumer report matches an event in the provider's Incident Reporting System, and if so, provide additional information. The data collected will then be analyzed to produce descriptive statistics.

I am the Director of the Health Law Program at the Earle Mack School of Law at Drexel University in Philadelphia. As part of teaching my Health Law I class this fall semester, my students and I worked on the problem of adverse event detection. We have read widely in the academic literature, have examined and discussed your proposal, and we offer some comments on the concept and strategies you may consider in the implementation of your proposal.

First, we concur that a patient based adverse event reporting system has value as an additional source of input on adverse events in health care institutions. We note that adverse event reporting to date has not proved very effective, missing a very high percentage of predicted adverse events. (Joel S. Weissman et al., *Comparing Patient-Reported Hospital Adverse Events with Medical Record Review: Do Patients Know Something That Hospitals Do Not?* ANN. INTER. MED. 2008;149:100-108, Table 4). Your proposed reporting system therefore has the

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potential, if systematically implemented, to add further data points in the search for adverse events, allowing a more accurate patient safety response aimed at reducing the rate of such events. We note that the literature on adverse event detection finds that it requires multiple strategies to get a full picture of the kind and level of such events in institutions. (See David W. Bates et al., *Policy and the Future of Adverse Event Detection Using Information Technology*, JAMA 10**:** 226, 226-27 (2003)).

We also note that there is considerable variation in adverse event definitions (see generally Barry Furrow, Adverse Events and Patient Injury: Coupling Detection, Disclosure, and Compensation, New Eng. L. Rev. 46: 437 (2012)). A common definition is "any injury caused by medical care." (*Glossary*, AHRQ Patient Safety Network, http://psnet.ahrq.gov/popup_glossary.aspx?name=adverseevent.) Distinctions between severe and minor events need to be clearly delineated for purposes of data collection and the grouping of patient harms. We conclude that the broadest possible definition, or scope of patient harms, should be used to create a useful data set.

Tracking rates of adverse event changes is challenging. As Pronovost et al, note, "A prime challenge in measuring safety is clarifying indicators that can be validly measured as rates. Most safety parameters are difficult or impossible to capture in the form of valid rates for several reasons: (1) events are uncommon (serious medication errors) or rare (wrong-site surgical procedure); (2) few have standardized definitions; (3) surveillance systems generally rely on self-reporting; (4) denominators (the populations at risk) are largely unknown; and (5) the time period for exposure (patient day or device day) is unspecified." (Peter J. Pronovost, Marlene R. Miller& Robert M. Wachter, *Tracking Progress in Patient Safety* JAMA 296: 696, 696 (2006)). Researchers are increasingly developing triangulating systems using multiple modalities to uncover adverse events. (Jennifer A. Taylor et al., *Triangulating Case-Finding Tools for Patient Safety Surveillance: A Cross-Sectional Case Study of Puncture/Laceration*, INJURY PREVENTION 17:388 (2011), *available at* http://injuryprevention.bmj.com/content/17/6/388.full.pdf+html.) The use of patient surveys of adverse events are likely to be a valuable addition, improving the calculation of rates of increase and decrease of events over time.

Second, we believe that a broad scope of solicitation of patient responses about adverse events is critical. Weismann et al concluded that adding adverse event questions to post discharge surveys of patients was an effective way of discovering additional information.(Weismann, 2008). The harder question is how to solicit such information in a multilayered opened way to maximize data about adverse events, from the smallest harms to the most severe. Your proposed system notes that "[t]he safety event intake form asks about a medical error or mistake, harm or injury as well as near misses." Your scope of questioning is broader than that used by Weisman et al. They defined their patient sourced events as "serious and preventable adverse events" in their study of the use of interviews of patients post discharge. Such a definition we believe is too narrow: it will miss both less serious and so-called nonpreventable events. If "near misses" are also defined with regard to such events, the possible universe of harms is too limited.

The idea that some patient harms are not preventable also makes an assumption about avoidability that creates a blindspot in the reporting system: it may miss harms that can in fact be prevented with the application of the right safety features. Focusing on avoidable medical errors and mistakes tends to draw attention away from a system focus at mismanagement of risk in the complex health care system. We note that your proposed intake form defines the scope of safety

events broadly, and we agree that the broadest possible solicitation of harms is preferable to narrower definitions. We are less convinced that questions about "near misses" will be useful. The AHRQ study should focus on those adverse events that have been or could be perceived by patients in the course of or following their treatment. Focusing on "near misses" will likely prove unsuccessful, as patients will, by definition, most likely be unaware that these events took place, unless told so by a staff member.

Third, we propose consideration of a multi-layered survey approach. The reporting system should be designed initially to elicit patient responses about their general experience in the hospital, within at first drawing their attention too quickly to particular severe harms they might have experienced. Follow-up surveys can look much more expansively at all adverse events, broadly defined, in order to produce a larger data set. Such a system should solicit general patient comments about satisfaction and hospital experience online or by telephone, without mentioning adverse events at first. As patients mention specific events, questionnaires and survey instruments should then pose more specific questions about harms a patient thinks he has experienced.

Fourth, we urge consideration of strategies to maximize patient participation in the process of submitted information, particularly online surveys. Incentives of various kinds might be considered, such as gift cards upon completion, to promote more complete reporting. The merits of a mobile application should also be evaluated. We note that while not all patients will have access to a computer, a higher percentage are likely to have access to web-equipped cell phones and other media devices. By developing a mobile app, researchers will be able to reach a broader sample of health care consumers and allow a greater number to provide responses on adverse events.

We further note that such reporting and survey tools are being applied to a large demographic of very different patients. We suggest that researchers, if they choose to continue using the web-based survey model, should repeatedly verify its validity and reliability to ensure that the largest number of people (of all different ages, educational levels, reading abilities and socioeconomic statuses) are able to comprehend the questions and provide the information the researchers are hoping to attain.

We hope that our comments will helpful to you as your proposal proceeds to implementation. If you have any questions, please feel free to contact us, using my email and other contact information.

Thank you.

Sincerely,

Barry R. Furrow

Sarah Bailey

Chelsea Biemiller

Ryan Loftus

Ashley Maguire

Elisa Boody
Krystyna Dereszowska
Tudor Farcas
Victoria Han
Tim Koch
Garrett Lambur
Trevor Serine
John Stringham
Victoria Suarez
Palmer Toto
Alex Yohay
Leah Zenou

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: A Prototype Consumer Reporting System for Patient Safety Events comments request
Date:	Friday, November 09, 2012 9:46:57 AM
Attachments:	FINAL Response to A Prototype Consumer Reporting System for Patient Safe....pdf

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From: Darryl Roberts [mailto:Darryl.Roberts@ana.org]
Sent: Wednesday, November 07, 2012 3:59 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: RE: A Prototype Consumer Reporting System for Patient Safety Events comments request

Dear Ms. Lefkowitz,

Please see the attached comment letter in response to the call for comments cited above.

Regards,

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November 9, 2012

Ms. Doris Lefkowitz
Reports Clearance Officer
Agency for Healthcare Research and Quality
540 Gaither Road, Suite 2000
Rockville, MD 20850

Submitted electronically to: doris.lefkowitz@ahrq.hhs.gov

RE: **A Prototype Consumer Reporting System for Patient Safety Events, Published September 10, 2012**

Dear Ms. Lefkowitz:

The American Nurses Association (ANA), which is the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses, appreciates the opportunity to respond to the Agency for Healthcare Research and Quality (AHRQ) request for funding the pilot project entitled, *A Prototype Consumer Reporting System for Patient Safety Events*. The project cites three goals: 1) To develop and design a prototype system to collect information about patient safety events; 2) To develop and test Web and telephone modes of a prototype questionnaire; and 3) To develop and test protocols for a follow-up survey of health care providers.

This project appears to have the best intentions; however, for the reasons presented below the ANA recommends that AHRQ complete additional improvement work prior to implementing a pilot project. Further, the ANA recommends that AHRQ invest in improving patient use of existing quality-related public reporting systems, such as Hospital Compare, Nursing Home Compare, and Home Health Compare, as well as improving self-reporting systems, such as health care organizations' advocacy or ombudsman programs, and Medicare Quality Improvement Organizations (QIOs), before engaging in pilots of new consumer reporting systems.

There are several effective methods in use for reporting patient safety events. For instance, many hospitals and health care systems employ patient representatives or ombudsmen. Medicare beneficiaries could report to QIOs. The AHRQ report does not mention the former and gives little discussion to the latter, even though these services facilitate collection of consumer and patient safety events and empower patients to present concerns and report events in a non-threatening and effective manner. Individuals knowledgeable of these and other extant methods to capture and mitigate error could provide AHRQ with valuable knowledge that could be used to improve and maximize the effectiveness of these resources before AHRQ resorts to development and testing of new methods.

The ANA suggests that AHRQ review the challenge promoted by the Office of the National Coordinator for Health Information Technology (ONC) to develop a handheld computer application (app) for reporting patient safety events[1]. The ONC notice cites several important criteria required for an app to win the challenge. Those criteria, while developed by another office within the Department

[1] Challenge.gov. Reporting Patient Safety Events (http://challenge.gov/ONC/349-reporting-patient-safety-events).

of Health and Human Services and for a different purpose, are sufficiently broad and integral to the success of any patient safety reporting system that AHRQ might benefit from including them in its own project. In the text of the challenge document, the ONC states, "…it is important to innovate beyond the existing tools so that a new system will:

1) Collect and analyze information that characterizes patient safety events in a standardized, discrete, measurable way
2) Increase the rate of reporting of patient safety events and improve the quality of the reported data
3) Leverage existing health information technology (HIT) to eliminate duplicate data entry, as well as transcription and transposition errors
4) Analyze patient safety event data to provide useful reports and actionable information to providers and PSOs"

As they currently read, neither the report nor the subsequent funding request sufficiently address or clarify how the pilot system might meet those criteria.

Other issues could limit the effectiveness of a pilot. First, AHRQ mentions, but does not specify, methods for patient engagement, data sharing, interoperability among systems, confidentiality of data, or public reporting of results. Further, the report does not address the potential for high costs associated with matching the reported error with the health care record. This matching could be particularly challenging and costly in paper-based or disparate electronic systems. Additionally, the report wisely recommends confidential data collection; however, the technical expert panel (TEP) also recommends an option to report anonymously. The TEP does not clarify how anonymous reports might contribute to error mitigation or reduction. Finally, AHRQ does not address protections that might need to be placed to prevent negative repercussions to individual clinicians named in any error reports.

In addition to overlooking the several existing methods of patient reporting, the report does not acknowledge or address the role of legal remedies. The ANA certainly does not endorse legal remedies for this purpose. However, ANA recognizes that many lawsuits arise from claims regarding medical errors. These can involve claims of malpractice, personal injury, and product liability contributing to personal injury or death. It could benefit AHRQ to acknowledge the presence of legal remedies and determine methods to mitigate errors before victims resort to legal remedies to effect changes. For example, AHRQ could investigate whether the proposed pilot would increase, decrease, or have no effect on the frequency of legal remedies. Moreover, the report should address how to protect the information collected by the system from improper usage in legal actions.

Most troubling is the fact that the survey questions or drafts of such questions are not included in the report. In a recent New York Times interview[2], Director Clancy gave some clues as to the content of several questions. The article reports one draft question that directs respondents to, "Tell us the name and address of the doctor, nurse or other health care provider involved in the mistake," indicating that this information and permission to share it with clinicians could improve safety. The article lists a series of possible responses to answer why an event occurred. These include:

[2] New System for Patients to Report Medical Mistakes (2012, September 22). New York Times. (http://www.nytimes.com/2012/09/23/health/new-system-for-patients-to-report-medical-mistakes.html?_r=0).

- "A doctor, nurse or other health care provider did not communicate well with the patient or the patient's family."
- "A health care provider didn't respect the patient's race, language or culture."
- "A health care provider didn't seem to care about the patient."
- "A health care provider was too busy."
- "A health care provider didn't spend enough time with the patient."
- "Health care providers failed to work together."
- "Health care providers were not aware of care received someplace else."

Unfortunately, these types of subjective and judgmental statements could misdirect respondents away from actually helping to solve the problem, but instead promote blaming an individual for the event. Additionally, none of the questions or answers cited adds valuable information from the reported incident that could inform a root cause analysis. Further, the questions and answers cited do not reflect the systems approach to error prevention and remediation effectively promoted by such organizations as The Institute of Medicine.

The ANA supports the idea of developing a method to improve consumer and patient access to an effective and non-judgmental method of detecting, reporting, and mitigating health care errors. As a profession, registered nurses are the most proximal and, therefore, most available clinicians providing for the health care needs of patients and their families. Registered nurses strongly advocate for the reduction of error and improvement of care structures, processes, and outcomes. In this case, the ANA does not believe that the current project is ready for piloting until it addresses the multiple issues cited above.

If we can be of further assistance, or if you have any questions or comments, please feel free to contact Darryl Roberts, Senior Policy Fellow, National Center for Nursing Quality at Darryl.roberts@ana.org or 301-628-5081.

Sincerely,

Marla J. Weston

Marla J. Weston, PhD, RN, FAAN
Chief Executive Officer
American Nurses Association

cc: ANA President Karen A. Daley, PhD, MPH, RN, FAAN

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Alert: New Task Assigned to Me and Others.
Date:	Friday, November 09, 2012 9:46:12 AM
Attachments:	Incoming 1460.pdf
Importance:	High

Comment

From: Nunley, Cindy E. (AHRQ)
Sent: Wednesday, November 07, 2012 4:30 PM
To: Lefkowitz, Doris C. (AHRQ)
Cc: Fatigati, Cathy (AHRQ)
Subject: FW: Alert: New Task Assigned to Me and Others.
Importance: High

Reminder....this was due today by 4:00. Please send your response to Cathy to close out the control. Thanks.

From: Nunley, Cindy E. (AHRQ)
Sent: Tuesday, November 06, 2012 2:50 PM
To: Lefkowitz, Doris C. (AHRQ)
Cc: Fatigati, Cathy (AHRQ)
Subject: FW: Alert: New Task Assigned to Me and Others.

Doris,

Here is the official control for the one Wendy has been asking about. It is due tomorrow, 11/7. Thanks.

Cindy

From: cts@ahrq.gov [mailto:cts@ahrq.gov]
Sent: Tuesday, November 06, 2012 2:39 PM
Subject: Alert: New Task Assigned to Me and Others.

AHRQ CTS

2012-C-1460 - CCC Task - Response
Assigned on Nov 6, 2012 2:39 PM EST.
Priority: Normal

View this Task

KEITH D. WASHINGTON
6265 MAGNOLIA RIDGE
STONE MOUNTAIN, GA 30087
EMAIL: kdwash@aol.com

September 27, 2012

Ms. Carolyn M. Clancy, Director
Agency for Healthcare Research and Quality
Office of Communications and Knowledge Transfer
540 Gaither Road, Suite 2000
Rockville, MD 20850.

Re: Quality & Patient Safety

I was pleased to read that the administration of President Obama wants consumers to report medical mistakes and/or unsafe practices by medical personnel and hospitals.

Attached for your review is a letter concerning Piedmont Hospital, Atlanta, Georgia, which I feel to be self-explanatory.

I feel strongly that as long as written permission must be obtained from the treating physician and/or hospital executive's before specific information regarding possible mistakes or unsafe practices can become public they will remain hidden and thus undermine your efforts.

I would appreciate your thought's regarding this matter.

Sincerely,

Keith D. Washington

Attachment

Quality Improvement Organizations

COPY

FINAL QUALITY OF CARE DETERMINATION TO THE BENEFICIARY

August 15, 2012

Mr. Keith Washington
6265 Magnolia Ridge
Stone Mountain, GA 30087

Re: Pauline Washington
DOS: 03/27/2011-03/28/2011
Provider: Piedmont Hospital

Dear Mr. Washington;

Alliant | GMCF is the Quality Improvement Organization (QIO) authorized by the Medicare program to review medical services provided to Medicare patients in the state of Georgia. By law, we review Medicare cases to determine if the services meet medically acceptable standards of care, are medically necessary, and are delivered in the most appropriate setting. We are also responsible for reviewing written complaints about quality of health care services received from a Medicare beneficiary or their representative.

Our primary purpose is to identify areas where care can be improved and provide feedback information to physicians and providers. In response to the initial written concern regarding your care, our QIO physicians have reviewed the medical records concerning the services your mother received on 03/27/2011 through 03/28/2011 at Piedmont Hospital.

Your concerns were:

- ***A urine sample was not obtained until several hours after your mother was admitted to the emergency room.***
- ***The emergency room nurse broke down crying claiming she was handling 8 patients and hated to give poor care.***
- ***Failure to diagnose a Urinary Tract Infection in a timely manner.***
- ***Congestive Heart failure listed as the cause of death on the Death Certificate.***

In response to your request, actively practicing, board certified, Alliant | GMCF physician consultants have reviewed your written complaints, the complete medical record, and correspondence from your physician.

COPY

As required by federal law, **42 CFR 480.105**, Alliant | GMCF gave the involved practitioner the opportunity to comment on our response concerning the healthcare services your mother was provided before issuing this letter.

"Federal regulations require that Alliant | GMCF receive written permission from the physician(s) involved in the case under review before specific information about the care is released. This applies whether our findings are positive or negative. In your case, such consent was requested but not provided, so we are unable to give you specific information about the findings of our review. This does not mean that problems were identified; if problems were identified, appropriate actions were taken."

Thank you for taking the time and effort to voice your concerns. Your desire to prevent this situation for others is admirable. We believe Medicare beneficiaries and their families help to improve the health care systems by openly and honestly sharing their concerns, as you did.

If you need further information or clarification, please contact Deirdre Davis, Medicare Review Nurse Consultant at 1-800-982-0411 option 2.

Sincerely,

Adrienne D. Mims, M.D. MPH
Medical Director
Georgia Medical Care Foundation
Quality Improvement Organization

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: AHRQ pilot study
Date:	Friday, November 09, 2012 9:45:00 AM
Attachments:	Regarding the NY Times article.docx

-----Original Message-----
From: Lisa Hess [mailto:lhess325@gmail.com]
Sent: Thursday, November 08, 2012 9:56 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: AHRQ pilot study

Dear Dr.Lefkowitz,

Thank-you very much for replying to my email regarding the AHRQ pilot study. I have attached a document with some alternative wording to the questions that the study presents in section 5 of the patient medical error reporting questionnaire. I appreciate you taking the time to review this document.

Sincerely,

Lisa Hess, MD
lhess325@gmail.com

255 North St
Iowa City, Ia 52246

Regarding the NY Times article: Pear, R. (2012,Sept.22) “New System for Patients to Report Medical Mistakes”.

As a practicing OB/Gyn. in Iowa, I am very interested in patient safety. Healthcare suffers from poor communication between patients and their providers, and the proposed survey tool could help. However, the language used to describe reasons for errors is adversarial at best and will serve only to exacerbate the problem. For example, the questionnaire offers: “A health care provider was too busy” as a possible cause of a medical error. The simple adjective “too” unnecessarily implies personal fault. Why not ask “Did you have enough time with your provider”? The way these “possible reasons for medical errors” are stated in the questionnaire continues the tradition of creating blame and shame when an error occurs, contributing to poor reporting of medical errors by healthcare providers. By removing the blame and emotional triggers in this questionnaire, the information received will be far more useful and effective.

Lisa Hess, MD

255 North St
Iowa City, Ia, 52246
lhess325@gmail.com
(319) 360-1725

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Proposed Information Collection - Consumer Reporting System for Patient Safety Events
Date:	Thursday, November 08, 2012 8:37:02 PM
Attachments:	AHRQ-reporting-OMBW.pdf

comments

From: Gavin Baker [gbaker@ombwatch.org]
Sent: Thursday, November 08, 2012 5:29 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Proposed Information Collection - Consumer Reporting System for Patient Safety Events

Ms. Lefkowitz,

Please see attached the comments of OMB Watch on the Agency for Healthcare Research and Quality's proposed information collection for a consumer reporting system for patient safety events.

Sincerely,

Gavin Baker
Federal Information Policy Analyst
OMB Watch
gbaker@ombwatch.org
Phone: (202) 683-4834
Twitter: @opengavin
LinkedIn: gavinrbaker

November 9, 2012

Ms. Doris Lefkowitz
Reports Clearance Officer
Agency for Healthcare Research and Quality
via email to doris.lefkowitz@AHRQ.hhs.gov

Re: Agency Information Collection Activities: Proposed Collection; Comment Request (77 FR 55475)

Dear Ms. Lefkowitz:

OMB Watch welcomes the opportunity to comment on the Agency for Healthcare Research and Quality's (AHRQ) proposed information collection. As a nonprofit organization dedicated to open government, accountability, and citizen participation since 1983, OMB Watch has long worked for effective government information collection practices and ready access to consumer information.

OMB Watch shares AHRQ's concern with improving patient safety and agrees that a consumer reporting system could "realize untapped potential of health care consumers to provide important information about patient safety events."[1] OMB Watch supports the development of a prototype system and encourages AHRQ to apply the lessons learned from the proposed information collection, if approved, toward the development of a national reporting system.

OMB Watch offers the following comments on the proposed information collection:

1. The proposed information collection will inform consumers and improve patient safety; and
2. Information sharing would enhance the utility of the proposed information collection.

1. The Proposed Information Collection Would Inform Consumers and Improve Patient Safety

OMB Watch believes that the proposed information collection would have practical utility in advancing AHRQ's health care research and information dissemination functions. OMB Watch agrees that "data about the consumer-reported patient safety events will be useful to the health care providers … in quality or performance improvement."[2] Therefore, OMB Watch encourages AHRQ to collect, analyze, and share the data with the health care providers.

[1] Notice.
[2] Supporting Statement A, p. 5.

1742 Connecticut Ave. NW
Washington, DC 20009
tel: 202.234.8494
fax: 202-234.8584
email: ombwatch@ombwatch.org
web: http://www.ombwatch.org

In addition, OMB Watch believes that even greater utility could be realized through additional uses of the data. Sharing the data with researchers, regulators, and the public would help to inform consumers and improve patient safety, as we explain below.

2. Information Sharing Would Enhance the Utility of the Proposed Information Collection

AHRQ should develop a plan to share the information proposed for collection. The agency's supporting statement addresses the confidentiality of the information[3] but does not address the issues of information sharing or public access. We agree that the consumer reports will be "highly valuable, even if not fully generalizable."[4] Therefore, we encourage AHRQ to explore ways to share the data with researchers, regulators, and the public.

Researchers: AHRQ should allow researchers outside the project team to analyze the data. Sharing the data with external researchers would enhance the utility of the information collected by facilitating more extensive research and additional analytic approaches. Researchers could then share their findings with health care providers, policymakers, and other researchers, who could apply the findings to improve patient safety. Researchers could also publicly report their findings, which would inform consumers about patient safety risks and trends. To protect confidentiality, AHRQ could provide full access only to qualified researchers who agree to keep the data secure, under a similar approach as the Qualified Entity Program conducted through the Centers for Medicare & Medicaid Services.

Regulators: AHRQ should share reports with relevant regulatory and law enforcement authorities at the federal, state, and local levels when a consumer reports a possible violation of law or regulation. Sharing reports with regulators could enhance enforcement, which could ultimately strengthen patient safety.

Public: AHRQ should explore ways to provide public access to the data. Consumer reporting databases can be valuable tools for the public, as demonstrated by other agencies already experienced in them. The National Highway Traffic Safety Administration (NHTSA), the Consumer Product Safety Commission (CPSC), and the Consumer Financial Protection Bureau (CFPB) have made non-confidential extracts of consumer reports accessible online in order to help the public make informed decisions. Disclosing consumer-reported data allows other consumers and their advocates to identify trends, avoid harmful products and services, and address problematic patterns. AHRQ should examine the feasibility of publicly disclosing non-confidential information about individual reports, as well as aggregate data.

[3] Supporting Statement A, p. 6-7.
[4] Supporting Statement A, p. 6.

AHRQ should consider the benefits of sharing the information collected, particularly if the prototype expands into a national system.

Conclusion

OMB Watch appreciates the opportunity to comment on AHRQ's proposed information collection. We hope you take our recommendations into consideration. If you have questions about our comments or want to discuss the issues further, please feel free to contact us.

Sincerely,

Sean Moulton
Director, Federal Information Policy
OMB Watch

Gavin R. Baker
Federal Information Policy Analyst
OMB Watch

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: GNYHA Comments on the Consumer Reporting System for Patient Safety
Date:	Thursday, November 08, 2012 1:11:23 PM
Attachments:	GNYHA Comments_CRSPS_lr eec.docx

From: Ryan, Lorraine [mailto:RYAN@GNYHA.org]
Sent: Thursday, November 08, 2012 1:08 PM
To: Lefkowitz, Doris C. (AHRQ)
Cc: Donohue, Kelly
Subject: GNYHA Comments on the Consumer Reporting System for Patient Safety

Dear Dr. Lefkowitz:

Attached please find GNYHA's comments on the proposed Consumer Reporting System for Patient Safety. Please feel free to contact me with any questions you may have.

In addition to these comments, I did have a question as to the eligibility and selection process for hospitals to participate in the analysis and research on the data derived from the reporting system.

Thank you.

Lorraine

Lorraine Ryan
Senior Vice President
Legal, Regulatory and Professional Affairs
Greater New York Hospital Association
555 West 57th Street
New York, NY 10019
Phone: 212-506-5416
Fax: 212-262-6350
E-mail: ryan@gnyha.org

Greater New York Hospital Association
555 West 57th Street / New York, N.Y. 10019 / (212) 246-7100 / FAX (212) 262-6350
Kenneth E. Raske, President

November
Eight
2 0 1 2

Doris Lefkowitz, Ph.D.
Reports Clearance Officer
AHRQ
540 Gaither Road, Room #5036
Rockville, Maryland 20850

RE: Comments on the Consumer Reporting System for Patient Safety

Dear Dr. Lefkowitz:

Greater New York Hospital Association (GNYHA) appreciates the opportunity to provide comments on the proposed Consumer Reporting System for Patient Safety. GNYHA represents approximately 250 hospitals and continuing care facilities in the New York metropolitan area, as well as throughout New York State, New Jersey, Connecticut, and Rhode Island. All of GNYHA's members are either not-for-profit, charitable organizations or publicly sponsored institutions.

GNYHA Focus on Patient Safety

GNYHA is a membership-driven organization, and in this regard, GNYHA has devoted and will continue to devote considerable resources to assisting our members with improving quality, patient safety, and efficiency through innovation, education, and collaboration among members, as well as with regulatory, accrediting, and professional bodies. In the past several years, these collaborations have led to decreased *C. difficile* infection rates, infection rates associated with central lines, better identification of sever sepsis and septic shock, and increased awareness of proper use of antibiotics among participating members. Most recently, GNYHA has partnered with the Healthcare Association of New York State (HANYS) to serve as a Hospital Engagement Network under the Partnership for Patients, a national initiative of the Centers for Medicare & Medicaid Services to advance its goals of better health, better care, and lower costs. Additionally, GNYHA has a long history of promoting transparency and public reporting to achieve better outcomes of care.

Incident Reporting in New York State

Since the 1980's, New York State had mandated that certain types of patient, staff, and environmental events by hospitals and licensed diagnostic and treatment centers be reported. The overall goal of incident reporting requirements is to improve the delivery of health care for all New Yorkers. Initially the focus of the incident reporting requirements was on accountability, but the focus has expanded and evolved into the New York Patient Occurrence Reporting and Tracking System (NYPORTS), a program that focuses on accountability, as well as quality improvement. GNYHA has been a part of an advisory body to the incident reporting program,

the NYPORTS Council, since its inception in 1999. GNYHA has also worked with the New York State Department of Health (DOH) for the last several years to refine and improve NYPORTS to ensure that it is an effective reporting system. The most recent revisions to NYPORTS were made in 2011 with the goal of promoting more complete reporting for the most serious types of cases.

Proposed Consumer Reporting System for Patient Safety

GNYHA supports the concept of collecting patient and family caregiver information about health care safety events to enhance the quality, appropriateness, and effectiveness of health services. The reporting system AHRQ proposes aims to collect information from patients and family members about medical errors that resulted, or nearly resulted, in harm or injury, known as "near misses," that are not currently collected by health care providers. Although GNYHA supports this concept, we have a number of concerns which are articulated below.

GNYHA and its members are concerned about the validity and reliability of the reports that will be entered into the proposed Consumer Reporting System for Patient Safety (CRSPS).

As outlined in the CRSPS Supporting Statement documents, it is not clear how the program's evaluators will distinguish between perceived lapses in care and actual medical errors and other health care safety events. GNYHA is concerned that patients and families may not be able to reliably distinguish a clinical complication or outcome of care that is not preventable from a preventable complication or medical error. The failure to screen out what may not be valid complaints or observations will negatively affect the integrity of the CRSPS program.

GNYHA believes there should be a mechanism for consistent and reliable health care provider follow-up on the reports consumers submit.

According to the Supporting Statement documents, CRSPS feedback to hospitals about complaints or reports that have been made about the hospital or other provider will only be made if the reporting patient or family member consents to that feedback being given to the provider. This will result in a body of data that is fragmented and incomplete. It will not meet the intended purpose of the CRSPS noted in the Supporting Statement as follows, "…such information is necessary for research on how to improve the quality of care, promote patient safety and reduce medical errors. There is a need to collect this information from consumers and match these consumer reports to the information collected by providers, because the two sources may differ. Examining data from both sources allows the project to determine to what extent patients are able to provide more complete or more detailed information." To meet this intent, reports must be shared with health care providers consistently and in all cases.

GNYHA and its members are concerned about the unwarranted and unintended increase in malpractice liability exposure that could result from the CRSPS.

The CRSPS has the potential to exacerbate and increase medical malpractice costs. The current medical malpractice system in this country is already fraught with invalid, baseless claims that result in unnecessary expense. In fact, studies indicate that 40% of medical malpractice claims involve no error, yet 28% of such no-error claims result in payments. GNYHA believes that the inability of consumers to distinguish preventable error from unavoidable complications of care secondary to patient co-morbidities will result in additional unwarranted and costly litigation.

In conclusion, GNYHA believes that the proposed CRSPS may provide valuable information to enhance quality and patient safety and identify effective methods of engaging consumers in reporting health-related safety events. However, the CRSPS must be constructed carefully, with

structured definitions of what should be reported, appropriate feedback mechanisms enabling providers to use consumers' information and observations to effectively improve systems and processes of care, and provider protections from unfounded and baseless complaints of adverse events.

GNYHA thanks AHRQ for inviting comments on the proposed CRSPS, and is available to provide additional feedback on the proposed system.

Please feel free to contact me with any questions you may have about these comments.

Very truly yours,

Lorraine Ryan
Senior Vice President, Legal,
Regulatory, and Professional Affairs
GNYHA
(212) 506-5416
ryan@gnyha.org

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Amerigroup Comments on "A Prototype Consumer Reporting System for Patient Safety Events"
Date:	Thursday, November 08, 2012 12:36:49 PM
Attachments:	Amerigroup Comments on AHRQ Consumer Reporting System _2012-11-8__FIN3.pdf
Importance:	High

comments

From: Gordon, Stuart [mailto:Stuart.Gordon@amerigroup.com]
Sent: Thursday, November 08, 2012 9:52 AM
To: Lefkowitz, Doris C. (AHRQ)
Cc: Oddo, Angel; Winiarek, Claire; Friedman, Merrill; Coyne, Brian
Subject: Amerigroup Comments on "A Prototype Consumer Reporting System for Patient Safety Events"

Importance: High

Ms. Lefkowitz –

Amerigroup thanks you for the opportunity to offer comments on the development of a Consumer Reporting System for Patient Safety (CRSPS) and on the proposed collection of consumer experiences. As a leader in coordinating and managing health care services and supports for the financially vulnerable, seniors and people with disabilities, we appreciate the Agency for Healthcare Research and Quality's (AHRQ's) work to advance this important issue and to do so with stakeholder and consumer engagement.

In our attached comments, we support the AHRQ's development and testing of a reporting system that captures consumers' experience with medical errors or mistakes. We believe the agency's development of a prototype CRSPS represents a strong first step in developing a practical framework for measuring and reporting on preventable occurrences. The prototype CRSPS, under development, will ensure the collection and availability of usable information for assessing the scope and scale of health care safety events in line with today's standards. We are supportive of the establishment of an effective monitoring and reporting system, and believe the prototype will have practical utility beyond the agency's own initiative; information collection can and should be shared publicly in support of related research, the development of evidence-based best practices and in assessing the efficacy of patient safety activities.

However, we are concerned the collection notice, as proposed, does not reflect a comprehensive use of new technologies, which may inhibit the quality, utility and clarity of the information to be collected. We also believe the employment of new technologies may minimize the time burden of the collection of information upon both consumer and provider respondents. Specifically, we recommend the final information collection use a smartphone and Internet or email-based approach, particularly for respondents serving low-income populations and who are themselves beneficiaries of an insurance affordability program.

Amerigroup has made significant investments in determining how best to connect with our low-income members and to solicit their input on issues relating to their health care services and care management. In recent years, due to the quantitatively demonstrated significance of smartphone

devices and the Internet in the day-to-day lives of financially vulnerable populations, we have advanced text messaging and social media campaigns to solicit a more engaged respondent base. Our smartphone-based information gathering campaigns have sometimes achieved response rates as high as 40 to 50 percent.

In our comments, we suggest that the AHRQ could determine the extent to which it should utilize these approaches by first asking respondents if they would be willing to provide their smartphone numbers or email addresses for purposes of sharing their experience with medical errors or mistakes. Those respondents affirmatively responding would be included in this approach to the survey. While we recognize there could be some concerns about the security and validity of responses electronically transmitted, the risks of disclosure and false results are likely to be no greater than would exist with the use of telephone surveys. We also note that these technologies can help create a streamlined, facile, accessible and less burdensome survey, likely to result in a more robust response.

If you have any questions or would like to discuss our comments further, please feel free to contact Angel Oddo, Amerigroup's Senior Vice President for Quality Management, at 757-769-7852 or by email to angel.oddo@amerigroup.com .

Again, thank you for the opportunity to offer our thoughts.

Stuart Yael Gordon
Director, Government Relations
Amerigroup
750 1st Street NE
Suite 1120
Washington, DC
phone: 202-218-4925
fax: 202-682-0786
cell: 202-213-4702
stuart.gordon@amerigroup.com
www.amerigroup.com

Amerigroup RealSolutions in healthcare

Nov. 8, 2012

Doris Lefkowitz
Reports Clearance Officer
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Rd.
Rockville, MD 20850

Submitted by email to doris.lefkowitz@ahrq.hhs.gov

Re: Agency Information Collection Activities: Proposed Information Collection; Prototype Consumer Reporting System for Patient Safety Events

Dear Ms. Lefkowitz:

On behalf of Amerigroup, we thank you for the opportunity to offer comments on the development of a Consumer Reporting System for Patient Safety (CRSPS) and on the proposed collection of consumer experiences. As a leader in coordinating and managing health care services and supports for the financially vulnerable, seniors and people with disabilities, we appreciate the Agency for Healthcare Research and Quality's (AHRQ's) work to advance this important issue and to do so with stakeholder and consumer engagement.

Amerigroup and our affiliated health plans coordinate health care services for approximately 2.7 million members in publicly funded health care programs, including Medicaid and the Children's Health Insurance Program, in 13 states across the country and in Medicare Advantage in eight states.[1] We are scheduled to begin offering Medicaid managed care services in the state of Kansas, our 14th state, in January 2013.

Let me first share that we support the AHRQ's development and testing of a reporting system that captures consumers' experience with medical errors or mistakes. We believe the agency's development of a prototype CRSPS represents a strong first step in developing a practical framework for measuring and reporting on these preventable occurrences. Amerigroup supports the creation of prevention and safety cultures that improve the delivery of health care and patient health outcomes by doing the following:

- Developing tools and providing education to support providers, stakeholders and consumers in their patient safety activities
- Establishing effective monitoring and reporting systems to identify patient safety issues in a timely manner

1. Membership as of June 30, 2012.

4425 Corporation Lane
Virginia Beach, VA 23462
757-490-6900

www.amerigroup.com

- Improving communication, linkages, transparency and information sharing to foster a prevention and safety culture
- Using evidence-based prevention and safety activities and the dissemination of best practices, to include a focus on national initiatives

The prototype CRSPS, under development, will ensure the collection and availability of usable information for assessing the scope and scale of health care safety events in line with today's standards. We are supportive of the establishment of an effective monitoring and reporting system, and believe the prototype will have practical utility beyond the agency's own initiative; information collection can and should be shared publicly in support of related research, the development of evidence-based best practices and in assessing the efficacy of patient safety activities.

However, we are concerned the collection notice, as proposed, does not reflect a comprehensive use of new technologies, which may inhibit the quality, utility and clarity of the information to be collected. We also believe the employment of new technologies may minimize the time burden of the collection of information upon both consumer and provider respondents. Specifically, we recommend the final information collection use a smartphone and Internet or email-based approach, particularly for respondents serving low-income populations and who are themselves beneficiaries of an insurance affordability program.

Amerigroup has made significant investments in determining how best to connect with our low-income members and to solicit their input on issues relating to their health care services and care management. In recent years, due to the quantitatively demonstrated significance of smartphone devices and the Internet in the day-to-day lives of financially vulnerable populations, we have advanced text messaging and social media campaigns to solicit a more engaged respondent base. Our smartphone-based information gathering campaigns have sometimes achieved response rates as high as 40 to 50 percent.

The AHRQ could determine the extent to which it should utilize these approaches by first asking respondents if they would be willing to provide their smartphone numbers or email addresses for purposes of sharing their experience with medical errors or mistakes. Those respondents affirmatively responding would be included in this approach to the survey. While we recognize there could be some concerns about the security and validity of responses electronically transmitted, the risks of disclosure and false results are likely to be no greater than would exist with the use of telephone surveys. We also note that these technologies can help create a streamlined, facile, accessible and less burdensome survey, likely to result in a more robust response.

Amerigroup commends the agency for its efforts to advance consumer reporting systems development transparently with robust stakeholder and consumer engagement. If you have any questions or would like to discuss our comments further, please feel free to contact me at 757-769-7852 or by email to angel.oddo@amerigroup.com.

Sincerely,

Angel Oddo
Senior Vice President, Quality Management
Amerigroup Corporation

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Comments on the proposed information collection project
Date:	Tuesday, November 06, 2012 8:54:02 AM

File with comments

-----Original Message-----
From: yy8@u.washington.edu [mailto:yy8@u.washington.edu]
Sent: Monday, November 05, 2012 9:45 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Comments on the proposed information collection project

Dear Ms. Lefkowitz,

I am writing in strong support of the proposed information collection project, "A Prototype Consumer Reporting System for Patient Safety Events."

As the daughter of a disabled elderly who was killed by a preventable medication error, I appreciate the concept to incorporate patients' experiences and perspective into the evaluation of quality of care. Time after time, it has shown that many healthcare providers and hospitals are not honest about medical errors and fail to report them. As documented in a recent report by the Office of the Inspector General, only 1% of adverse events are actually reported by hospitals.

If we want to improve the quality of medical care and patient safety, this problem of under reporting by medical professionals must be changed.

In this modern world with tons of medical information available, patients are getting smarter and are more informed than ever. They have a very good sense of what happens in their care and to their bodies, and what is right and what is wrong. In an article published by Zhu et al. in 2011, it shows that over 70% of adverse events reported by patients are accurate. However, many doctors and hospitals, even including state medical boards tend to discount patients' reports. Often, they label the patients who complain as being trouble makers. This kind of attitude by the healthcare providers and hospitals are self-serving, to say the least.

So, I am so glad to see AHRQ is taking this important step in the right direction because it is long overdue to listen to patients about the quality of their own care. Furthermore, the patients' reports will provide additional information on patient safety, invaluable for improving medical quality. As a volunteer patient safety advocate, I would be happy to help test out the proposed patient reporting system.

The following are some detailed suggestions to the proposed "CRSPS Intake Reporting Form":

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1. In SECTION 3: MISTAKE: "3.1 Did the medical mistake or error involve any of the following? D. A mistake related to a diagnosis, or treatment, or advice from a doctor, nurse, or other healthcare providers":

***** I recommend adding the word "treatment" in category D.

2. Under 3.1.1 related to medication:

***** I recommend adding two questions that relate to medication:
"Was the prescribed medication used off label?"
"Was the prescribed medication contraindicative to any medical conditions?"

3. Under 4.2.1. "What kind of physical negative effect did the patient experience?"
~~~~~~

***** I recommend adding several more categories here:

(a) Worsened existing medical conditions;
(b) heart failure;
(c) respiratory failure;
(d) kidney failure;
(e) bedsores;
(f) permanent damage;
(g) disabled;
(h) death

4. Under SECTION 5: "CONTRIBUTING FACTORS, CHANGES IN CARE, DISCOVERY, & REPORTING 5.1. Why do you think this mistake or negative effect happened?"

***** I recommend adding a category related to the competency of health care providers.

~~~~~~

Please let me know if you have any questions regarding my comments. Thank you for your assistance.

Best Regards,

Yanling Yu
3941 NE 158th lane
Seattle, WA 98155
yy8@uw.edu
206-366-1629

Yanling Yu, PH. D
University of Washington
616 NE Northlake Place
Seattle, WA 98105
Phone: 206-543-1254
~~~~~~

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: patient reports on medical errors
Date:	Monday, November 05, 2012 8:53:40 AM

comments

From: ShirlLinde@aol.com [mailto:ShirlLinde@aol.com]
Sent: Friday, November 02, 2012 5:55 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: patient reports on medical errors

Excellent idea. Should be simple, short, and not be connected or implied to be connected with potential lawsuits. A simple form given at discharge with option of gong to a website (save postage). Last question: what do you think could havae been, if anything, to prevent the problem that you had?

Stress that not designed to get physicians or other staff into trouble, but to improve patient care.

Perhaps outpatients should be included also.

Shirley Linde
MedicalInformationCenter.org
ShirleyLinde.com

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: RESPONSE TO FEDERAL REGISTER NOTICE # 2012-22028
Date:	Friday, November 02, 2012 8:40:36 AM
Attachments:	Carolyn Clancy Letter Nov 2012draft (2).pdf

File with comments

From: Mike Cohen [mailto:mcohen@ismp.org]
Sent: Thursday, November 01, 2012 4:14 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: RESPONSE TO FEDERAL REGISTER NOTICE # 2012-22028

Please accept this response to Federal Register Notice # 2012-22028, regarding the proposed project, A Prototype Consumer Reporting System for Patient Safety Events.

Thank you.

Michael R. Cohen

ISMP is a federally certified patient safety organization (PSO).

Visit our consumer website and sign up for customized medication safety alerts:
http://www.consumermedsafety.org

Mike Cohen
Institute for Safe Medication Practices
200 Lakeside Drive, Suite 200
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e-mail: mcohen@ismp.org
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A NONPROFIT ORGANIZATION

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November 1, 2012

Carolyn Clancy, MD
Director
Agency for Healthcare Research and Quality

In care of: Doris Lefkowitz,
Reports Clearance Officer, AHRQ
doris.lefkowitz@AHRQ.hhs.gov.

RESPONSE TO FEDERAL REGISTER NOTICE # 2012-22028

Dear Dr. Clancy:

The Institute for Safe Medication Practices (ISMP) would like to comment on the September 10, 2012, *Federal Register* notice regarding the development of a prototype consumer reporting system for patient safety (CRSPS). ISMP has three primary concerns that we feel should be addressed before moving forward—the program's apparent punitive focus as it relates to collection of reports, lack of a plan to use the reports for learning and safety improvements, and a failure to coordinate efforts with existing consumer reporting programs.

Comments on CRSPS

Issue #1: Punitive focus. The CRSPS plan suggests that consumers will be asked to identify individual healthcare providers involved in the reported events and that these healthcare providers will be contacted to provide additional information about these events. ISMP has several concerns with this reporting format. First, it perpetuates a punitive culture of finger-pointing and suggests to the consumer that action will be taken against individuals involved in the errors, particularly given that the current CRSPS plan does not describe any other actions that may result from the reporting program, such as learning about the system-based causes of errors and recommending strategies that may reduce the risk of errors (see Issue #2). In its current state, the reporting program appears to be a mechanism for consumers to report healthcare providers who have made errors, with a promise to consumers to put the healthcare providers on notice about their unacceptable lack of perfect performance. The current format also conveys the misconception that individuals are wholly responsible for errors, disregarding the influences of system design and the environment that play a large role in human error and behavioral choices. In addition, healthcare providers who are contacted after a consumer has reported an error will naturally be defensive about the event. It would not be a far reach to assume that these individuals will feel as though they and their organizations have been "reported" to the government and are now being summoned to defend themselves. The usefulness of the information from healthcare providers will likely be compromised by defensive posturing rather than cooperation to uncover behavioral choices and system design issues that contributed to the error.

Issue #2: Use of reports to improve safety. The CRSPS plan presented in the *Federal Register* says the demonstration project will "record data from consumers," but does not take the next crucial step and indicate how the reports received will be evaluated, analyzed, shared with a broader audience, and used in any way to enhance learning or improve safety. As is, the plan calls only for reporting without sufficient planning of expert analysis of the data, dissemination of lessons learned, and use of the information to improve safety. Our common

goal in terms of patient safety should be to provide healthcare professionals, the medical products industry and the general public with realistic prevention strategies to help stop mistakes and adverse events from occurring. If CRSPS collects new data, but it is never reviewed by experts who can pass on new insights about safety risks, then the reporting program ultimately will have no impact on error prevention. Again, its only perceived purpose may be to report "bad" healthcare providers who have made an error.

Collaboration with other existing programs. The CRSPS plan also does not mention any collaboration with other federal agencies or patient safety organizations to ensure that data will be consolidated with other existing consumer reporting programs. For example, ISMP currently has an agreement with another federal agency—The US Food and Drug Administration (FDA)—to share safety information and material on our respective consumer websites. In addition, ISMP and FDA have established an open line of communication regarding our respective analysis of the data provided by our respective consumer reporting programs, which has resulted in a powerful alliance when crucial drug safety information and recommendations need to be communicated to the healthcare community and consumers at large. This kind of collaboration best serves patients by making sure that a common, accessible body of knowledge is formed and used to its fullest capabilities to guide improvements.

Background on ISMP consumer reporting program. ISMP was founded decades ago to uncover more about medication errors happening across the nation, understand their causes, advocate for safe practices and share "lessons learned." The Institute has had extensive experience with error reporting, including operating a non-governmental national voluntary medication error-reporting program for healthcare professionals. Since 2008, ISMP has operated an active consumer medication error-reporting program on its consumer website at http://www.consumermedsafety.org and also accepts telephone calls from consumers. A registered nurse is employed to handle the website and consumer telephone calls. The ISMP reporting program for consumers is accessed at: http://www.consumermedsafety.org/report-a-medication-error. ISMP has shared safety recommendations based on consumer reports with the entire healthcare community through its newsletters and websites and journal columns. The Institute also educates the healthcare community weekly or more often through its "Check-up" blog on Philly.com (http://www.philly.com/philly/health/97905324.html), the Philadelphia Inquirer's website, as well as in the newspaper itself when appropriate. The Institute provides all of these services at no cost to the American taxpayer.

FDA also operates an active consumer section of the FDA.gov website and a reporting program for consumers. The Agency has formally partnered with ISMP to share reports of medication errors and promote safety improvements (http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM297672.pdf). Consumer reports to ISMP have sometimes resulted in FDA public health advisories or other actions.

We hope that AHRQ will dedicate additional time and resources to evaluation, safety advocacy for needed changes, and communication of data gained through CRSPS, so that it will ultimately have an impact and provide a benefit in safeguarding healthcare consumers.

Sincerely,

Michael R. Cohen, RPh, MS, ScD (hon), DPS (hon)
President

MRC/ls

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: AHRQ Comment on Proposed Program via the Rand Corporation to monitor "doctor errors"
Date:	Thursday, November 01, 2012 1:37:53 PM

comments

From: Bert Cobb [mailto:bert.cobb@gmail.com]
Sent: Thursday, November 01, 2012 12:04 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: AHRQ Comment on Proposed Program via the Rand Corporation to monitor "doctor errors"

Dear AHRQ (Ms. Doris Lefkowitz, Reports Clearance Officer),

With the limited resources for providing health care and the number of doctors leaving medicine because of bureaucracy, how will this "program" in any way alleviate the shortages? My fellow doctors find this demeaning and a further barrier between patients and providers. It ASSUMES errors WILL BE COMMITTED a priori when the FACTS are otherwise. Government intrusion into medicine is KILLING the practice of medicine and the strong bond of patients with THEIR doctors. This is but another example of more paperwork that will not enhance the quality of health care. The attorneys will LOVE for you to identify potential lawsuits FOR THEM. In Texas, we work under the aegis of The Texas State Board of Medical Examiners. They are the most demanding and stringent "masters" one could imagine. We are held to the highest standards of practice and behavior with oversight from medical and lay board members who LOVE to punish physicians. Now you want to do the same NATIONALLY and MAKE us comply? Are you nuts are merely misguided? Trash the idea and let Rand Corporation do something realistic and that will IMPROVE medical care and ADD to the number of providers. Stay out of medicine because you know NOTHING of its rigors, requirements and dedication. This is INSULTING. For a change, why don't you ASK YOUR DOCTOR how he or she feels about your "program"? Ask quickly because this program may be the straw that breaks the camel's back and they QUIT.

Sincerely yours,

Bert Cobb, M.D.
P.O. Box
San Marcos, Texas 78667-0913

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: AOA letter concerning CRSPS prototype
Date:	Wednesday, October 31, 2012 2:07:14 PM
Attachments:	AOA AHRQ Prototype comments 103112.pdf

From: Monaco, Carol [mailto:CMonaco@osteopathic.org]
Sent: Wednesday, October 31, 2012 1:36 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: AOA letter concerning CRSPS prototype

Hello Ms. Lefkowitz,

The AOA is submitting comments on AHRQ's Prototype Consumer Reporting System for Patient Safety Events. Please see the attachment. Thank you.

Carol Monaco
Director of Federal Affairs
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AOA: TREATING OUR FAMILY AND YOURS

AMERICAN OSTEOPATHIC ASSOCIATION

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October 31, 2012

Carolyn Clancy, M.D., Director
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850
Submitted electronically via: doris.lefkowitz@AHRQ.hhs.gov

Re: AHRQ Prototype Consumer Reporting System for Patient Safety Events

Dear Dr. Clancy,

The American Osteopathic Association (AOA), which represents more than 100,000 osteopathic physicians and medical students, appreciates the opportunity to comment on the Agency for Healthcare Research and Quality's (AHRQ) proposed Consumer Reporting System for Patient Safety Events (CRSPS). The AOA commends AHRQ for its efforts to design and test a system for collecting information from patients about health care safety events following standard definitions and formats. There is no doubt that patients provide a unique and valuable perspective on health care and that patient reports could complement and enhance provider input and thus produce a more complete and accurate understanding of the prevalence and characteristics of medical errors.

While we appreciate the agency's efforts to provide transparency in hopes of reducing medical errors, we have several concerns about the proposal. While some medical errors are obvious, other outcomes are not so clear cut and therefore if reported as errors could mischaracterize the medical event and produce inaccurate information. In addition, we are concerned about the limitations of patient-centered data collection tools. If not properly worded, not in a format that users can easily understand, and not properly paired with provider-reported data, these tools may result in inaccurate information about patient safety events, excessive and misinformed malpractice claims, and other actions that could unnecessarily harm the reputation of well-intentioned health professionals.

Over time, these unintended consequences could result in higher healthcare costs and lower quality due to mistrust and frustration among health professionals in systems meant to improve care, all of which, we believe, is the exact opposite of AHRQ's intent. As AHRQ moves forward with efforts to enhance the role of patient-reported data, the AOA requests that the agency keep in mind the concerns outlined in this letter.

General Concerns

The document refers to adverse medical events and mistakes. How does ARHQ define adverse medical event? It is possible to have an adverse medical event without it being a mistake. A patient's condition may not respond well to medication or a procedure provided by the physician. A

patient responding poorly to a treatment is not necessarily the result of a mistake. Does the patient have enough medical knowledge to be able to identify and determine what caused an adverse medical event as well as differentiate a mistake?

Through the CRSPS, AHRQ aims to collect patient-reported data on the details of a safety concern, including when, where, and whether there was harm; the type of harm; contributing factors; and whether the patient reported the event and to whom. While these are all valuable questions that can provide important insight into quality, we worry about questions that rely heavily on what may too often be conjecture rather than empirical evidence. While some medical "mistakes" are black and white and can be easily identified by a patient (e.g., did your physician mix you up with another patient? did your physician prescribe you a medicine to which you are allergic?), most are not.

Even questions as simple as "did you receive the wrong medicine or the wrong dose of medicine" can be misinterpreted if the patient receives a therapeutically equivalent or generic drug with a different name than was originally prescribed. The patient may not understand that the dispensed drug and its adjusted dosage is an equal substitute to the originally prescribed drug. Similarly, a physician may need to modify his/her care plan midway through a procedure due to unforeseen events or discoveries. This is especially common in surgery. A patient may interpret such events as having the "wrong surgery performed" even though the adjustment was clinically justified and most likely resulted in better, more targeted care.

As such, we are concerned about questions that ask patients about whether they received the wrong diagnosis or advice. While many patients are engaged stakeholders who seek out information regarding clinical diagnoses, symptoms, and treatments, most simply do not have the same level of expertise as clinically trained professionals and may not have the knowledge base to determine whether a diagnosis was "wrong" or why the diagnosis may have changed during the course of care. We recognize that these challenges could be mitigated with proper communication between the patient and physician. For example, if a physician clearly explains to a patient that he is prescribing a therapeutically equivalent drug because it is cheaper and has fewer side effects, the patient would not be alarmed when the bottle listed a different name or dosage for the drug. However, the CRSPS, as currently written, does not sufficiently capture whether and to what extent these conversations occurred.

The AOA is equally concerned about questions that ask patients about "contributing factors." We are concerned that, in some (but certainly not all) cases, a patient or family member may not have the clinical knowledge base or sufficient understanding of the healthcare system to accurately identify why a mistake happened. In question #5.1 of the web-intake form, for example, the survey asks the patient to identify why a mistake or negative effect may have happened and then provides the patient with a list of reasons to choose from, instructing the patient to "check all that apply." This strategy essentially feeds patients answers that may sound logical and appropriate on paper, but which may have never crossed the patient's mind or may have had very little or nothing to do with the original incident. Additionally, some of the reasons, such as "health care provider was too busy" or "health care providers failed to work together," seem to rely more heavily on subjective rather than objective conclusions. Even if a patient claims to have directly observed a "busy" provider, it is difficult for the patient to know with certainty that an incident occurred as a direct result of the provider being too busy. Will those who fill out this survey be required to provide documentation to support their claims? Would the selection of answers provide the data necessary to pinpoint the cause of medical errors?

Despite these concerns, the AOA believes that many of the reasons listed as answers to question #5.1 on the web-intake form, such as "health care provider did not communicate well with patient" or "health care providers did not follow up with the patient" are important factors to consider that can provide valuable insight for providers and minimize the chance of these incidents occurring again in the future. As such, we recommend that AHRQ keep this question open-ended rather than supplying patients with pre-constructed reasons for why an incident may have occurred. This would give patients the opportunity to explain in their own words why an incident may have happened and, if applicable, to acknowledge that they are not sure about the reasons why. Analysts could then go back and evaluate which category of reason a patient's response falls into in order to identify patterns across healthcare settings regarding potential contributors to medical mistakes. While this strategy would not necessarily work in a more scientific study, AHRQ mentions multiple times in its supporting statements to the Office of Management and Budget (OMB) that "this is not a statistical survey, but a convenience sample for a demonstration project" that will help AHRQ to better understand effective methods of engaging consumers in reporting health-related safety events, both through structured *and* narrative reports. Therefore, we believe that heavier reliance on open-ended questions is appropriate and necessary.

Specific Recommendations

Listed below are brief comments and suggestions about other specific survey questions. All question numbers refer to the web version of the intake form:

3.1.2.2. Did the mistake with a test, procedure, or surgery involve any of the following? PLEASE CHECK ALL THAT APPLY

In line with our previously stated concerns, we believe that some of the responses to this question may be too subjective, such as "the test, procedure, or surgery was delayed unnecessarily" and "it took too long for the patient to get the results." The same wait time may be interpreted by one patient as appropriate while another may view it as inappropriate.

3.1.3.1 Did the mistake with the diagnosis or medical advice involve any of the following? PLEASE CHECK ALL THAT APPLY.

- Wrong diagnosis
- Delayed diagnosis
- Bad medical advice
- Something else _____

Again, this question rests much too heavily on subjectivity and may be widely interpreted by patients. At the very least, we recommend that AHRQ explicitly define the terms "wrong diagnosis" and "delayed diagnosis" or at least request that patients provide their own definition or more detailed explanation should they check either of these boxes. We also recommend that AHRQ simply remove the term "bad medical advice" since it is much too vague to result in any useful information. We believe that patients would have the opportunity to discuss what they interpret as "bad medical advice" in the open ended final question.

3.3 Would you like to tell us the name and address of the health care doctor, nurse, or other health care provider (or the health care facility) involved in the mistake?

While this information could serve an important purpose if reported accurately, the AOA is concerned about patients who may wrongly identify a provider when they are unsure of who, exactly, was involved in the incident. For example, if there was a perceived delayed or mis-diagnosis and the reasons for this were not explained to the patient, how would the patient know whether it was the fault of the physician, the lab interpreting the test results, or another member of the healthcare team? Furthermore, many delays and other incidents are often the result of system-wide failures and not necessarily the fault of any single care provider. The current response choices for this question are "yes" or "no." To minimize these concerns, we recommend that AHRQ at least add a third response that states, "I am not sure who was involved in the mistake."

3.4 How did the patient find out that the mistake [or negative effect] happened? (Please choose the one answer that fits best.)

- **The patient noticed it.**
- **A friend or family member noticed it and told the patient.**
- **A doctor, nurse, or other health care provider told the patient about it.**
- **An administrator or manager told the patient about it.**
- **The patient found out in some other way. →How did patient find out?**
- **The patient never knew about it.**

The AOA believes this question is critically important since it will help determine the accuracy or at least the level of subjectivity that may have factored into the patient's other responses, which we expressed concerns about above. Collecting this information will also allow AHRQ to better match patient reports with information collected by providers, to determine the extent to which these two sources may differ, and to develop ways to ascertain more complete or more detailed information from patients. We cannot overemphasize the importance of matching patient reported data with information provided by healthcare professionals and documented in medical records.

3.5 Did a doctor, nurse, or other health care provider make any special effort to help the patient handle the mistake?

- **Yes**
- **No**
- **Don't know**

3.7.1 Did it help?

- **Yes**
- **No**
- **Don't know**

While we believe these questions focus on important information, we feel they could result in even more useful data if they asked the patient to explain, in his/her own words, how the provider made a special effort to help the patient handle the mistake.

3.8 Did the mistake [or negative effect] affect the patient financially?

Again, this question should ask the patient to explain exactly how it affected them financially since the question, as currently stated, is open to broad interpretation. The more detailed information gleaned from the patient, the better policymakers will understand the factors contributing to safety events and medical mistakes and the effect they have on patients.

4.2.1 What kind of physical negative effect did the patient experience? PLEASE CHECK ALL THAT APPLY.

- **Dizziness**
- **Sick to the stomach (nausea)**
- **Infection**
- **Pain**
- **A fall that caused an injury**
- **Open sores on skin**
- **A sexual problem**
- **Blood clot**
- **Uncontrolled bleeding**
- **Breathing difficulty**
- **Numbness or weakness**
- **Injury to teeth**
- **Injury to an eye**
- **Burn**
- **Heart attack or stroke**
- **Other physical effect____**
- **The negative effect was not physical**

Many of these answer choices do not accurately capture the reason for the negative effect. For example, open sores or an infection could be the result of patient noncompliance with wound care. Furthermore, many of these physical effects may be unrelated to the original procedure even though to the patient they appear to be related.

5.2 Is there anything else that caused the mistake or negative effect to happen?

The AOA recommends that AHRQ modify this statement so it reads, "Is there anything else that *may have* caused the mistake or negative effect to happen?"

Additional Factors

We are concerned that this questionnaire, although it has good intentions, could lead to misleading information about the health care provider's quality of care. How will this information be quantified? Will documentation back up the claims? What protections will be provided to the physician or hospital against false claims? The questionnaire raises other questions. For example, how exactly will the federal government use this information; to what extent will this information be made public; how will the privacy of the patients and providers be protected; can this information be used in medical malpractice lawsuits?

The AOA encourages AHRQ to keep in mind that while the current lack of patient reporting mechanisms may contribute to a large number of adverse medical events that continue to go unreported, it is not the only contributing factor and not the only part of the system that needs to be improved in order to minimize medical errors. Healthcare professionals fear career-threatening disciplinary actions and possible malpractice litigation, and clinicians working in a culture of blame and punishment do not report all errors. The current system, which does not always protect

reporters of errors or near misses from negative consequences, only reinforces this fear. While AHRQ assures protections of confidentiality for the patient under this pilot, it is not clear to what extent healthcare professionals will be protected. As such, we are greatly concerned that AHRQ's proposed patient safety reporting system could give rise to greater malpractice suits, increase the cost of liability insurance, and decrease the quality of health care for the patient.

We thank AHRQ for its tireless efforts to date to implement the provisions of the Patient Safety and Quality Improvement Act of 2005, which encourages clinicians and health care organizations to voluntarily report and share quality and patient safety information without fear of legal discovery. We believe this is a step in the right direction, and we look forward to working with AHRQ to develop Common Formats for other settings, such as physician offices. Still, many healthcare organizations continue to find it challenging to provide an environment in which it is safe to admit errors and understand why the errors occurred. We encourage AHRQ to continue working towards a system that encourages a culture of safety rather than individual blame. Reporting should take place in a confidential, non-punitive environment that incorporates follow-up actions, which foster education and promote iterative system improvements.

The AOA appreciates AHRQ embarking on this important project, and we look forward to working with the agency to promote patient-reported data and to minimize safety events in healthcare. Should AHRQ have any questions about our comments, please feel free to contact: Carol Monaco, AOA Director of Federal Affairs, at 202-414-0145.

Sincerely,

Ray E. Stowers, DO
AOA President

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Agency for Healthcare Research and Quality Agency Information Collection Activities: Proposed Collection; Comment Request
Date:	Wednesday, October 31, 2012 10:24:23 AM

comments

From: Flashner, Gary M. (ELS-STP) [mailto:garyf@exitcare.com]
Sent: Monday, October 29, 2012 1:47 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Agency for Healthcare Research and Quality Agency Information Collection Activities: Proposed Collection; Comment Request

Dear Ms. Lefkowitz:

I am writing in response to the Comment Request posted in the Federal Register on October 5, 2012 as regards the AHRQ Information Collection Activities (https://www.federalregister.gov/articles/2012/10/05/2012-24454/agency-for-healthcare-research-and-quality-agency-information-collection-activities-proposed).

I serve as Vice President of Medical Content for ExitCare, an Elsevier company that develops, maintains, and translates a library of health education materials. I speak for our entire Minnesota-based organization by saying that we appreciate the opportunity to provide feedback and suggestions regarding the project and tasks outlined by the AHRQ.

ExitCare completely agrees with the following statements by the AHRQ:

> "In order to fulfill the promise of EHRs for all patients, especially for persons with limited health literacy, clinicians should have a method to determine how easy a health education material is for patients to understand and act on, have access to a library of easy-to-understand and actionable materials, understand the relevant capabilities and features of EHRs to provide effective patient education, and be made aware of these resources and information."

ExitCare respectfully disagrees with the following premise that is included in the Federal Register posting:

> "However, health education materials delivered by EHRs, when available, are rarely written in a way that is understandable and actionable for patients with basic or below basic health literacy."

After a careful and detailed analysis, it was determined that, in order to provide productive feedback regarding the validity of the HIRS, suggested revisions for the HIRS, and the associated estimated burden, it would be most helpful if the AHRQ would clarify a few items:

1. What criteria did the TEP use to determine "understandability" and "actionability" when rating the 12 patient education materials that were

evaluated? It is important to note that quantifiable factors used for the development of effective print material are different than those used to develop audiovisual material.

2. What is the background of those on the Technical Expert Panel? Is the group made up of clinicians, professional educators, others?

Thank you for your time and attention. We look forward to your feedback.

Sincerely,

Gary M. Flashner, M.S. M.D. ABFP
Vice President, Medical Content
Elsevier/ExitCare

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From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Patient reporting of errors mostly a bad idea.
Date:	Thursday, October 25, 2012 8:47:51 AM

comment

From: coreydm@frontier.com [mailto:coreydm@frontier.com]
Sent: Wednesday, October 24, 2012 8:48 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Patient reporting of errors mostly a bad idea.

I'm a registered nurse in a private hospital in Oregon (btw, there's only two) and I always strive for perfection in my practice. I also sometimes catch flack for taking too much time to provide superior care in whatever I do. Let's be frank, most hospital errors occur because there is just simple too much work to be done by too few of staff(including physicians and nursing). I would love to think that patient reporting of errors is a wonderful idea and that it would lead to hospitals' upper management being held accountable for inappropriate staffing levels to help reduce errors. But let me tell you, many of these patients we take care of would be completely unreliable to be trusted to report errors accurately. Many patients are sick because of diagnosed and undiagnosed mental conditions they suffer from and are very unhealthy mentally and nutritionally. Comparatively, you are much less likely to see a well-adjusted, "normal" adult sick in the hospital, there's a reason for that. Then you have the very biased family equation to mix in. Many family members of sick people whether they be elderly, spousal, or children, just aren't as rational in these situations as they are in the rest of their lives(believe me, I've been there several times). Also, you must take into account that most just don't understand enough about medical care to know even if an error occurred or even how to report it to where anybody can understand the information. You will also see major abuses of the reporting from chronically dissatisfied people.

My suggestion is to have an error reporting law/system where medical professionals can report errors they see easily and confidentially in addition to the current organized reporting systems now in place. I assure you, most professional healthcare workers would want to report what goes on if they believe it would lead to better care and hence a better environment to work in. It would also be important that specific information not be requested since this could be traced back to a department and an employee trying to do the right thing. Maybe a third part of this system can be a patient reporting of errors, but this could make it less likely that a staff member would want to report an error too because it could lead to identification of the reporting staff member.

My two cents,

Corey RN

From:	Robbie
To:	Roemer, Marc I. (AHRQ)
Subject:	Re: A Prototype Consumer Reporting System for Patient Safety Events
Date:	Friday, September 28, 2012 12:19:31 PM

---

aren't u a sweetie.

Could u plssssss forward my note to d lefkowitz.

I worked in the system until my retirement and I can tell you that nothing-zero will come of this study. That is why people are so bold in harming patients and also why incidents are not reported.

The only thing that will change this nonsense is elevating patient boldness by EDUCATING THE PATIENT. Lack of knowledge and courage will kill in the medical field. Please greed to that list.

-----Original Message-----
From: Roemer, Marc I. (AHRQ)
Sent: Friday, September 28, 2012 6:49 AM Subject: A Prototype Consumer Reporting System for Patient Safety Events

We received your note describing your experience with the medical care system. The recent articles in the news media that you referred to in your letter described a pilot study that AHRQ expects to conduct next year.

At this time, AHRQ has announced this new activity in the Federal Register and is open to receiving comments through November 9, 2012. The Federal Register Notice as well as documents describing the study are attached to this letter. If you wish to submit comments about this project you may send them to Doris Lefkowitz at AHRQ through email. Her email address is doris.lefkowitz@ahrq.hhs.gov.

Thank you for your interest in AHRQ and in this important project.

Marc Roemer
Agency for Healthcare Research and Quality
Marc.Roemer@ahrq.hhs.gov

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Agency for Healthcare Research and Quality"s (AHRQ) public commentary
Date:	Tuesday, October 16, 2012 10:16:45 AM

comment

From: Tami [mailto:tjmccrystal@hotmail.com]
Sent: Monday, October 15, 2012 4:41 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Agency for Healthcare Research and Quality's (AHRQ) public commentary

Doris,

I think this is a WONDERFUL reporting system for the patient, as well as the family health advocate.

I would have loved to have this system in place to report several incidences of error when my mother was in the hospital.

Consumers of health care should have this reporting system to make everyone aware of each facilities margin of error.

I feel the proposed system could very well serve the public, as well as a grade marker for hospitals to ensure better care and follow-up.

I strongly support the implementation of a central healthcare reporting system.

Sincerely,
Tami McCrystal

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: CTS-1503
Date:	Wednesday, October 24, 2012 2:42:47 PM
Attachments:	2012-C-1503.zip

Comments

From: Nunley, Cindy E. (AHRQ)
Sent: Wednesday, October 24, 2012 10:42 AM
To: Lefkowitz, Doris C. (AHRQ)
Subject: FW: CTS-1503

Reminder…this is due today. Thanks.

From: Fatigati, Cathy (AHRQ)
Sent: Friday, October 12, 2012 10:16 AM
To: Lefkowitz, Doris C. (AHRQ)
Cc: Nunley, Cindy E. (AHRQ)
Subject: CTS-1503

Hi Doris,

This CTS from the OD was addressed to you for response. The **due date** is 10/24/2012.

Secretary's Correspondence

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
EXECUTIVE SECRETARIAT

OS#:	**092520121006**	*Date on Letter:*	**9/23/2012**
From:	**Hess, Lisa (Lhess325@gmail.com)**		
City/State:	**Cedar Rapids IA**	*Date Received:*	**9/25/2012**
On Behalf Of:	**,**	*Type:*	**General Public**
Subject:	**EMAIL: Writer raises her concerns with language that is used to desccribe the possible 'reasons' for medical errors. She feels that the options are adversarial at best. Healthcare already suffers from poor communication between patients and their healthcare providers and she provide possible alternatives. She requests a response back to her concerns and comments.**		
Synopsis:			
Subject Tags:	**email**		

Assigned to:	**AHRQ**		
PC:	**Lauren Underwood**	*Date Assigned:*	**9/27/2012**
Action Required:	**Direct Reply**	*Date Reassigned:*	**10/11/2012**
		Reply Due Date:	**10/25/2012**

Info Copies To: **Lisa Bauman; Underwood, Lauren (HHS/IOS)**

Interim (Y/N): **No** *Date Interim Sent:*

Comments: **10/11/12--Per CMS: The New York Times composed an article based on the White House drafting a Pilot where consumers would report medical mistakes. The article prompted the writer to submit a letter which comments on language used in the drafted reporting system (questionnaire). The pilot is awaiting approval from the White house and has not been assigned to an Agency. CMS reviewed this request and we determined that this control does not fall in our purview. We suggest OS/ES check with AHRQ. Thanks! LO**

File Index: *CCC:* **Laura ONeill**

Department of Health and Human Services
Office of the Secretary
Executive Secretariat

Information Copy

Date:	**10/11/2012**	*OS#:*	**092520121006**
Assigned Agency(s):	**AHRQ**	*Task Type:*	**Initial Authoring**
Task Recipient(s):	**CMS; AHRQ**	*Action Required:*	**Direct Reply**
Information Copies:	**Lisa Bauman; Underwood, Lauren (HHS/IOS)**		
Assigned PC:	**Underwood, Lauren** **Policy Coordinator**		
Subject:	**Secretary's Correspondence**		
	Incoming from: Lisa Hess **EMAIL: Writer raises her concerns with language that is used to desccribe the possible 'reasons' for medical errors. She feels that the options are adversarial at best. Healthcare already suffers from poor communication between patients and their healthcare providers and she provide possible alternatives. She requests a response back to her concerns and comments.**		
Synopsis:			
Subject Tags:	**email**		
File Index:		*CCC:*	**ONeill, Laura**

Information Only; No Action Required

Instructions: The New York Times composed an article based on the White House drafting a Pilot where consumers would report medical mistakes. The article prompted the writer to submit a letter which comments on language used in the drafted reporting system (questionnaire). The pilot is awaiting approval from the White house and has not been assigned to an Agency. CMS reviewed this request and we determined that this control does not fall in our purview. We suggest OS/ES check with AHRQ. Thanks!

Thank you for your cooperation.

Attachments

From: Sebelius, Kathleen (HHS/OS) [Kathleen.Sebelius@hhs.gov]
Sent: Sunday, September 23, 2012 3.17 PM
To: OS Oshhsexecsec2
Subject: FW: Patient safety

From: Lisa Hess[SMTP:LHESS325@GMAIL.COM]
Sent: Sunday, September 23, 2012 3:16:49 PM
To: Sebelius, Kathleen (HHS/OS)
Subject: Patient safety
Auto forwarded by a Rule

The Honorable Kathleen Sebelius,

I am writing in regards to a recent NY times article describing a pilot project to encourage patients and family members to report medical errors. (Pear, R. (2012,Sept.22) New System for Patients to Report Medical Mistakes. *The New York Times.* Retrieved from http://nyti.ms/QuZhjD). I am a practicing OB/Gyn. in Cedar Rapids, Iowa and am very interested in improving patient safety. I agree that it is important to engage patients and their families in this process. I am intrigued by the pilot project that is described where patients or family members can respond to a questionnaire regarding possible medical errors. The article states that the questionnaire asks "why the mistake happened and lists possible reasons:

"A doctor, nurse or other health care provider did not communicate well with the patient or the patient's family."

"A health care provider didn't respect the patient's race, language or culture."

"A health care provider didn't seem to care about the patient."

"A health care provider was too busy."

"A health care provider didn't spend enough time with the patient."

"Health care providers failed to work together."

"Health care providers were not aware of care received someplace else."

My concern is the language that is used to describe the possible "reasons" for medical errors. I feel that the options are adversarial at best. Healthcare already suffers from poor communication between patients and their healthcare providers and I feel that the way these "possible reasons for medical errors" are stated continues the tradition of creating blame and shame when an error occurs which, I feel, is why adverse medical events are poorly reported. This culture of blaming and shaming the healthcare team

when adverse events occur also contributes to the adversarial relationship between patients and healthcare providers.

I have recently started a Masters program in Dispute and Conflict Resolution through Creighton University. In this program we learn about how important it is to communicate clearly and also how difficult this is to achieve. We studied an interesting example of successful dispute resolution policies within the online company eBay. eBay was able to create a dispute resolution system that now handles tens of millions of disputes yearly with great participant satisfaction. One of the most important things that contributed to the success of this program was the way disputes were described. Rather then stating "sender did not ship item" they provided a category "item not received", likewise disputes regarding lack of payment by the buyer were no longer categorized as "deadbeat buyer" but as "payment not received" (Rule, C. (2008, Fall). Making Peace on eBay: Resolving Disputes in the World's Largest Marketplace. *ACResolution.* Retrieved from www.ACRnet.org.). By removing the aspect of blame inherent in the original terms, the emotional component of the dispute was dissipated and the actual problem could be addressed. I feel this is a tool that this project could benefit from. Rather than stating "(a) health care provider didn't respect the patient's race, language or culture" why not ask:

"Did you feel that there was difficulty communicating with the healthcare team?

Was the difficulty due to:

Terminology: it was difficult to understand what the healthcare team was saying because of medical terminology.

Language: English is not my native language or, English was not my doctor'/nurse's native language- he/she had an accent I could not understand.

Culture: I was uncomfortable with the health care team's medical treatment plan because it required me to do things that I don't believe are right."

Likewise the phrase "(h)ealth care providers failed to work together" could be transformed into "Did you feel you healthcare team had all the information they needed to take care of you? If no, which sentence best characterizes your situation?

I felt that the healthcare team did not have the information from the tests I had performed during my current hospitalization.

I felt that the healthcare team did not have information from my doctor's office.

I felt the healthcare team did not have information from my previous hospital stays."

By removing the blame and emotional triggers in the wording of the questions, the information that is received will likely be more useful for addressing medical "errors" and will also establish a working relationship between patients, their families and their healthcare teams to provide safe medical care.

Thank-you for your time and consideration and I look forward to your response,

Sincerely,

Lisa Hess, MD

lhess325@gmail.com

Initial Authoring Round 1 Response 2416385.1 from CMS[1]

The New York Times composed an article based on the White House drafting a Pilot where consumers would report medical mistakes. The article prompted the writer to submit a letter which comments on language used in the drafted reporting system (questionnaire). The pilot is awaiting approval from the White house and has not been assigned to an Agency. CMS reviewed this request and we determined that this control does not fall in our purview. We suggest OS/ES check with AHRQ. Thanks!

New System for Patients to Report Medical Mistakes

By ROBERT PEAR
Published: September 22, 2012

WASHINGTON — The Obama administration wants consumers to report medical mistakes and unsafe practices by doctors, hospitals, pharmacists and others who provide treatment.

"Patient reports could complement and enhance reports from providers" about errors, Dr. Carolyn M. Clancy said.

Hospitals say they are receptive to the idea, despite concerns about malpractice liability and possible financial penalties for poor performance.

In a flier drafted for the project, the government asks: "Have you recently experienced a medical mistake? Do you have concerns about the safety of your health care?" And it urges patients to contact a new "consumer reporting system for patient safety." The government says it will use information submitted by patients to make health care safer.

Federal officials say that medical mistakes often go unreported, and that patients have potentially useful information that could expose reasons for drug mix-ups, surgery on the wrong body part, radiation overdoses and myriad other problems that cause injuries, infections and tens of thousands of deaths each year.

Hospitals and even some doctors say the proposal has merit. "It's a great concept," said Nancy E. Foster, a vice president of the American Hospital Association. "The idea is welcome."

A draft questionnaire asks patients to "tell us the name and address of the doctor, nurse or other health care provider involved in the mistake." And it asks patients for permission to share the reports with health care providers "so they can learn about what went wrong and improve safety."

In seeking White House approval this month for a prototype of the reporting system, Dr. Carolyn M. Clancy, the director of the federal Agency for Healthcare Research and Quality, a part of the Public Health Service, said, "Currently there is no mechanism for consumers to report information about patient safety events."

"Patient reports could complement and enhance reports from providers and thus produce a more complete and accurate understanding of the prevalence and characteristics" of medical errors, Dr. Clancy said.

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September 10, 2012

Federal officials said the reports would be analyzed by researchers from the RAND Corporation and the ECRI Institute, a nonprofit organization that has been investigating medical errors for four decades.

Dr. Kevin J. Bozic, the chairman of the Council on Research and Quality at the American Academy of Orthopaedic Surgeons, said it was important to match the patients' reports with information in medical records.

"Patients' perceptions and experience of care are very important in assessing the overall success of medical treatments," Dr. Bozic said. "However, patients may mischaracterize an outcome as an adverse event or complication because they lack specific medical knowledge.

"For instance, a patient may say, 'I had an infection after surgery' because the wound was red. But most red wounds are not infected. Or a patient says, 'My hip dislocated' because it made a popping sound. But that's a normal sensation after hip replacement surgery."

Consumer groups welcomed the federal initiative. The American Medical Association had no immediate comment, saying it needed to study the details.

Some research suggests that one-fourth of patients in and out of hospitals experience "adverse events" in their care. Hospital patients interviewed by researchers in Massachusetts reported many events that were not documented in their medical records.

In the reporting system envisioned by the Obama administration, patients and their relatives would report medical errors and near misses through a Web site and in telephone interviews.

For each incident, the government wants to know "what happened; details of the event; when, where, whether there was harm; the type of harm; contributing factors; and whether the patient reported the event and to whom."

The questionnaire asks why the mistake happened and lists possible reasons:

¶ "A doctor, nurse or other health care provider did not communicate well with the patient or the patient's family."

¶ "A health care provider didn't respect the patient's race, language or culture."

¶ "A health care provider didn't seem to care about the patient."

¶ "A health care provider was too busy."

¶ "A health care provider didn't spend enough time with the patient."

¶ "Health care providers failed to work together."

¶ "Health care providers were not aware of care received someplace else."

If the pilot project is cleared by the White House, health officials hope to start collecting information in May. Questionnaires would be made available at kiosks in hospitals and doctors' offices. Fliers describing the project would be given out at pharmacies and mailed to patients' homes with the explanation of benefits sent to them by insurance companies.

Reporting is voluntary, and federal officials said they would keep the information confidential.

A government script for follow-up interviews explains: "A medical mistake or error is an act or omission by a health care provider that most health care providers would consider incorrect at the time it happened. Some, but not all, medical mistakes can result in harm or injury to the patient."

The government wants to know if the mistake involved the wrong medicine, the wrong dose of medicine or reactions to a drug; the wrong test or procedure, the wrong diagnosis or surgery on the wrong body part; or blood clots, infections, problems with anesthesia or "unclean or unsanitary care."

Martin J. Hatlie, the chief executive of Project Patient Care, a health care safety coalition in Chicago, welcomed the federal plan.

"Patients and their families are a potential gold mine of information," Mr. Hatlie said. "They see things that busy health care workers don't see. Doctors are in and out. Nurses are in and out. But relatives are there continuously with the patient. They often know how to fix problems that cause errors."

In recent years, Congress has taken steps to link Medicare and Medicaid payments to the quality of care, prohibiting payment for the treatment of certain medical errors.

A version of this article appeared in print on September 23, 2012, on page A20 of the New York edition with the headline: New System for Patients to Report Medical Mistakes.

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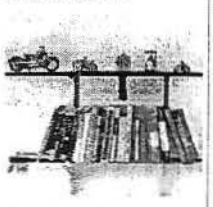
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From: Sebelius, Kathleen (HHS/OS) [Kathleen.Sebelius@hhs.gov]
Sent: Sunday, September 23, 2012 3.17 PM
To: OS Oshhsexecsec2
Subject: FW: Patient safety

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Sent: Sunday, September 23, 2012 3:16:49 PM
To: Sebelius, Kathleen (HHS/OS)
Subject: Patient safety
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Thank-you for your time and consideration and I look forward to your response,

Sincerely,

Lisa Hess, MD

lhess325@gmail.com

Secretary's Correspondence

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
EXECUTIVE SECRETARIAT

OS#:	**092520121006**	*Date on Letter:*	**9/23/2012**
From:	**Hess, Lisa (Lhess325@gmail.com)**		
City/State:	**Cedar Rapids IA**	*Date Received:*	**9/25/2012**
On Behalf Of:	**,**	*Type:*	**General Public**
Subject:	**EMAIL: Writer raises her concerns with language that is used to desccribe the possible 'reasons' for medical errors. She feels that the options are adversarial at best. Healthcare already suffers from poor communication between patients and their healthcare providers and she provide possible alternatives. She requests a response back to her concerns and comments.**		
Synopsis:			
Subject Tags:	**email**		

Assigned to:	**CMS**		
PC:	**Lisa Bauman**	*Date Assigned:*	**9/27/2012**
Action Required:	**Direct Reply**	*Date Reassigned:*	
		Reply Due Date:	**10/12/2012**

Info Copies To:	**Lisa Bauman**		
Interim (Y/N):	**No**	*Date Interim Sent:*	
Comments:			
File Index:		*CCC:*	**Laura ONeill**

CTS Summary for 2012-C-1503

Control Information

Control Number:	2012-C-1503	**Date Created:**	10/11/2012 2:55 PM EDT
OS/ES Control:	Yes	**Tracer ID:**	092520121006
Congressional Control:	No	**OGC Control:**	No
Webmail:	No	**OCKT Tracking Number:**	
Incoming/Received Date	10/11/2012	**AHRQ Due Date:**	10/24/2012
Subject:	OS - EMAIL: Writer raises her concerns with language that is used to desccribe the possible 'reasons' for medical errors. She feels that the options are adversarial at best. Healthcare already suffers from poor communication between patients and their healthcare providers and she provide possible alternatives. She requests a response back to her concerns and comments.		
Control From:	Lauren Underwood	**Control From Organization:**	Office of the Secretary
Control To:	Carolyn Clancy	**Control To Organization:**	AHRQ
Comments:			

Assignment Information

Lead Office (for multiple centers):		**Assigned Center or Supporting Office(s):**	CFACT
Assignment Type:	Prepare Response for IOD DIR or D/Dir	**Office Center Summary for:**	CFACT
Special Instructions:	Attn: (Leftkowitz) Note: Please do not send response directly from CFACT. Prepare response for Dr. Clancy and return to IOD.		
Office Center Action Taken Comments:			
Office of Exec Sec Comments:			
Concur Response:		**Concur Person:**	

Yellow Sheet

Center Office	Who	Date

Date Completed: null **Summary updated on:** 10/11/2012

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Comment: "A Prototype Consumer Reporting System for Patient Safety Events."
Date:	Monday, October 22, 2012 10:12:32 AM

File with comments

From: actorveronica@aol.com [mailto:actorveronica@aol.com]
Sent: Thursday, October 18, 2012 10:11 AM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Comment: "A Prototype Consumer Reporting System for Patient Safety Events."

Dear Ms. Lefkowits:

Thank you so very much for undertaking this endeavor. Patient access to successfully report patient safety data including adverse events, near misses, HAI's and other Sentinel Events is crucial to the overall health of our world, not just this country. Our very lives and values are at stake, and are being severely compromised by greed, incompetence, and negligent behaviors throughout the systems that is meant to Heal us. Too often, patients -- the focus and most important members of any healthcare team -- are overlooked, and our comments and valid complaints are swept under the carpet and hidden in veils of unethical and unlawful secrecy, all in the name of profit.

We must end the harmful practice of gagging victims who choose to settle out of court:

http://www.jdsupra.com/post/documentViewer.aspx?fid=ec220299-34be-4548-82a2-7574f360b64e

To that end I created this:

http://www.thepetitionsite.com/426/911/456/end-the-silence-ban-gag-clauses-in-medical-settlements/

Here is my Mom's story of CITED negligent care:

http://nurseup.com/wordpress/2012/04/my-mothers-story-by-veronica-eliscu/

Please work to implement this needed system of safe and effective reporting and follow up ASAP. Yor own life and those of your families are at stake!

Thank you.
Respectively,

Veronica Eliscu
Paramus, NJ

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Medical Error Central Reporting System
Date:	Monday, October 22, 2012 9:45:58 AM

A comment

From: Joe & Chris Guilfoyle [mailto:cguilfoyle1@verizon.net]
Sent: Sunday, October 21, 2012 10:18 AM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Medical Error Central Reporting System

Dear Ms. Lefkowitz,

Please put me down as a supporter of the proposed Medical Error/Adverse Event central reporting system. I believe it is an excellent idea in light of the current underreporting of such incidents.

Thank you,
J.C. Guilfoyle

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Request for Comment "A Prototype Consumer Reporting System for Patient Safety Events."
Date:	Monday, October 15, 2012 10:10:35 AM

From: Terri Lewis [mailto:tlm7291@siu.edu]
Sent: Saturday, October 13, 2012 6:37 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: RE: Request for Comment "A Prototype Consumer Reporting System for Patient Safety Events."

Doris Lefkowitz, Reports Clearance Officer, AHRQ,

doris.lefkowitz@AHRQ.hhs.gov

RE: Request for Comment "A Prototype Consumer Reporting System for Patient Safety Events." Rulemaking.

I completely support the goals of this project and believe it is necessary to improve the performance of oversight of consumer health care practices.

1. Safety event intake form and follow up. I cannot express strongly enough the need for adverse event reporting. We cannot understand our successes if we do not understand our medical errors, i.e, mistakes, harm or injury, and near misses. This procedure should allow any patient who is subject to an error to voluntarily report safety events through a Web site or by telephone. The questions ask what happened, details of the event, when, where, whether there was harm, the type of harm, contributing factors, informed consent and disclosure, whether the treatment was coerced or other options denied, and whether the patient reported the event and to whom. Information should be collected regarding whether the respondent is willing to have CRSPS staff follow up to clarify information. If a respondent consents, CRSPS staff should be able to follow up by phone, or a field visit, and ask questions about any information that was not clear in the initial report and annotate the report with this information. Reports and findings should be posted to the state regulatory board that governs the practitioner's license.

2. Health care provider follow up. For the subset of consumers that consent, patient safety officers at health care provider organizations who maintain the adverse event reporting system will contribute supplemental information about the consumer-reported incident which occurred at their facility. CRSPS staff will contact the health care organization to share the consumer report with the patient safety officer or other appointed liaison. The liaison will determine if the consumer-reported incident matches an event in the provider's Incident Reporting System, and if so, provide additional information. Providers should provide written protocols for management of the procedures that are reported as adverse events and where negative outcomes are confirmed, a plan of corrective action shall be filed for review along with evidence of implementation.

Collected data collected should be analyzed to produce estimates and basic descriptive statistics on the quantity and type of consumer-reported patient safety

events, examine the variability of responses to questions, examine the mode of data collection by event types, and conduct correlations, cross tabulations of responses and other statistical analysis.

The proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, and makes a practical contribution to understanding health care costs, services, opportunities for improvement, and regulatory maintenance. This information has practical utility for consumers, providers and regulators. The accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information appears to be sound. This should integrated as a component to Electronic Health Records Systems in order to enhance the quality, utility, and clarity of the information to be collected and to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology. Submitted reports and their resolution should be maintained in patient files for examination and confirmation and should require that patient's receive a copy and confirm with their signature.

Very Respectfully,
Terri A Lewis
Health Care advocate
931-267-3532
Tal7291@yahoo.com or tlm7291@siu.edu
1061 E Park, Apt 12
Carbondale, IL 62901

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	Fw: AHRQ Central Reporting System
Date:	Friday, October 12, 2012 3:40:00 PM

File with comments on the medical error project

From: Susan Shure [mailto:susan.shure@gmail.com]
Sent: Friday, October 12, 2012 02:48 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: AHRQ Central Reporting System

To Whom It May Concern:

I am writing to express my support for the proposed reporting system. We can't do a proper job of repairing and improving our health care system without accurate data. Personally, I trust no one as much as I trust myself to accurately report adverse events. And because of my personal experiences, I know just how much can go wrong in that setting. I have always been an informed consumer of my own health care. I would really appreciate having the tools to help improve health care for everyone.

Thank you for your attention to this matter.

Susan Shure

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: medical mistakes
Date:	Friday, October 12, 2012 1:30:41 PM

File with comments

From: dennis sievers [mailto:sieversd_50@yahoo.com]
Sent: Friday, October 12, 2012 1:23 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: medical mistakes

I strongly support the institution of a medical mistakes reporting system that does not depend on hospitals and doctors alone. A universal reporting system would put a greater responsibility on the health system to make general improvements that would serve and protect the medical consumer.

Dennis Sievers
2323 w 10th St.
Davenport, IA 52804

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: My comment on hospital Report
Date:	Friday, October 12, 2012 11:21:27 AM

From: Lural Carwell [mailto:carwelljanejordan68@gmail.com]
Sent: Friday, October 12, 2012 10:29 AM
To: Lefkowitz, Doris C. (AHRQ)
Subject: My comment on hospital Report

I think this is an excellent program. I just wish hospitals could be honest about what happens in their workplace,we all will eventually experience being in the hospital. I usually check with the D-magazine for top hospitals in Dallas area.

Lural J Carwell

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Prototype Consumer Reporting System for Patient Safety
Date:	Friday, October 05, 2012 12:21:27 PM
Attachments:	Consumer Reporting System for Patient Safety.pdf ATT00001.htm Common Vision IJAIP0303-0403 SINGH.pdf ATT00002.htm

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From: Gurdev Singh [mailto:gsingh4@buffalo.edu]
Sent: Friday, October 05, 2012 12:18 PM
To: Lefkowitz, Doris C. (AHRQ)
Cc: Munier, William (AHRQ); Ranjit Singh; Thomas C Rosenthal; John Taylor; Diana Anderson; Gurdev Singh
Subject: Prototype Consumer Reporting System for Patient Safety

Dear Dr. Lefkowitz,
Following my approach to Dr. Clancy, I have been encouraged by Dr. Munier to write to you my comments on the AHRQ proposal.
Having read through the 11 attachments kindly sent by Dr. Munier I would like to submit the

attached comments. Also attached is a paper that is referred to in my comments.

With kindest regards,

gurdev

Gurdev Singh BScEngg (Alig) MScEng PhD (Birm)

Director, UB Patient Safety Research Center
Adjunct Professor UB School of Management
Fellow of the Royal Society of Medicine (London)
Member of the WHO Expert Panel on Patient Safety in Primary Care

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"It is important for the leaders to do right things and their teams to do things right"

Creating a common vision for all stakeholders to make healthcare safer with interactive visual modelling

Ranjit Singh*

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Abstract: Medical errors are a major cause of harm to patients. The World Health Organization has, therefore, formed an Alliance for Patient Safety. Reports on error are a rich source for understanding of causes, cascades and consequences. Improvements in safety can result through lessons learnt from these. There are loud and clear calls for the development of appropriate error reporting and taxonomy systems, that are useful at the point of care and policy levels. The urgency expressed in these calls presents a challenge and an opportunity to harness the power of computer visualisation that can help structure and illustrate the 'story' of an error in a universal language. This can overcome the shortcomings of current reporting methods and help create an unambiguous international error taxonomy. Presented here is a concept for a web-based visual error reporting system. Although the ambulatory care domain is used for illustration, this concept can provide a user-friendly, efficient means of reporting errors in any domain of healthcare. This unambiguous structured visual modelling, aided by touch-screen technology, is useful to all members of healthcare teams, especially policymakers and patients. Patients particularly are a major source of knowledge on the state of safety in all healthcare settings that is waiting to be tapped.

Keywords: common vision; healthcare; interactive; modelling; safety; visual.

Reference to this paper should be made as follows: Singh, R., Singh, A., Singh, S. and Singh, G. (2011) 'Creating a common vision for all stakeholders to make healthcare safer with interactive visual modelling', *Int. J. Advanced Intelligence Paradigms*, Vol. 3, Nos. 3/4, pp.223–239.

Biographical notes: Ranjit Singh is a graduate of the University of Cambridge, England, where he read medicine and management. He is the Associate Director of Patient Safety Research Center, State University of New York at Buffalo, USA. He has authored numerous papers. He has served on national expert committee and AHRQ review panels.

Ashok Singh is a graduate of the University of Cambridge, England where he read medicine and management. He is the Medical Director of Quality, Niagara Falls Memorial Medical Center and Partner, Niagara Family Medicine Associates, Niagara Falls. He has authored papers on patient safety and simulation.

Sonjoy Singh is a graduate of the University of Cambridge, England, where he read medicine. He is a Partner of The Niagara Family Medicine Associates, Niagara Falls, NY, USA. He is recipient of Western New York 'Top Doctors' awards and has authored papers on patient safety and simulation.

Gurdev Singh is the Founding Director of Patient Safety Research Center at State University of New York at Buffalo, USA. In 1996, he was recognised by the US Department of Justice as an 'Alien of Extraordinary Ability'. This classification is awarded to a person who has demonstrated that she/he has reached the top of her/his profession at the international level for a sustained period of time, or to a Nobel Laureate or equivalent. He is also a Fellow of the Royal Society of Medicine, London. His experience and themes of his publications include: development and use of hybrid decision support systems, multidisciplinary appraisal of risk and reliability in healthcare, project management and structures based on Monte Carlo simulation, multi-objective and multi-resource optimisation and 'satisfisation', development of Singh-Markowitz efficient frontier method, concurrent engineering, stochastic and visual simulation of construction projects, and computer-aided learning of risk and reliability analysis.

This article is a revised and expanded version of a paper entitled 'Visual modeling for making healthcare safer' presented at North-American Simulation Technology Conference (NASTEC) 2009, held at the Georgia Tech Global Learning Center, Atlanta, USA on 26–28 August 2009. It has been revised and updated.

1 Introduction

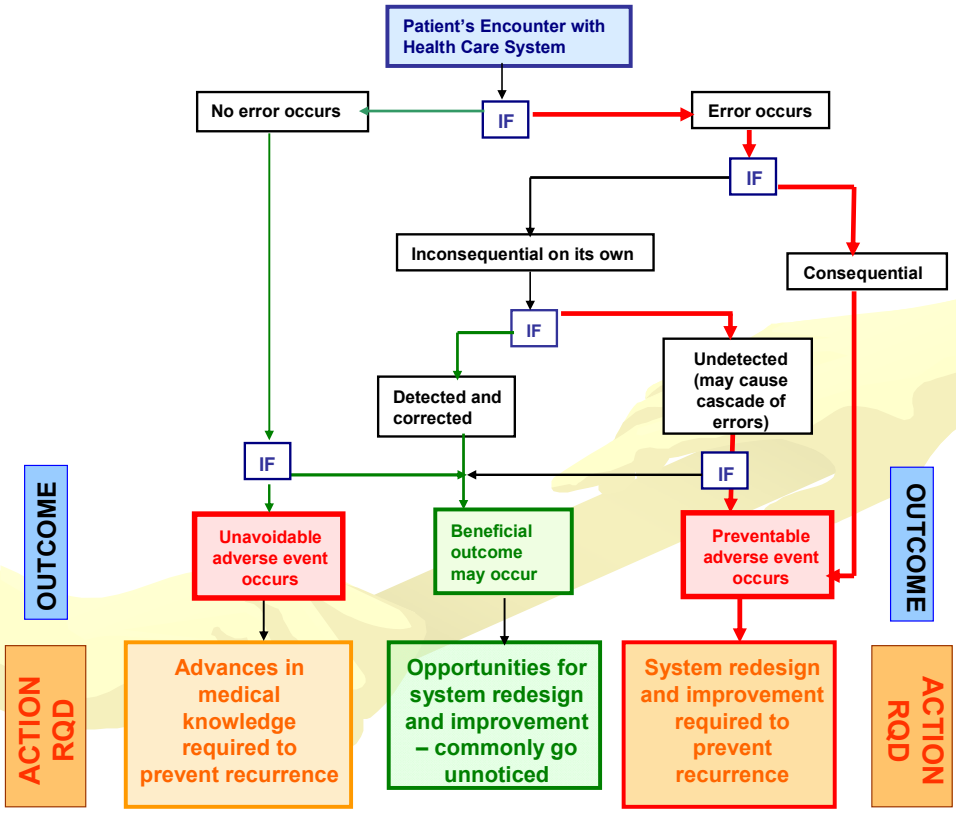
Creation of a culture of safety is a critical first step for healthcare organisations that truly wish to improve quality and safety (Kohn et al., 2000; Singh et al., 2009a, 2009b). One of the steps in developing a culture of safety is the recognition by staff, clinicians and patients of errors that occur on a regular basis (Joseph et al., 2007). A prime driver for achieving this recognition is error reporting. Reporting systems need to be safe (that is, free from blame), easy, and worthwhile (Billings, 1998; Leape and Arbookire, 2005). In the USA, the Patient Safety and Quality Improvement Act of 2005 (Patient Safety and

Quality Improvement Act, United States Public Law 109-41, 2005) is intended to encourage and facilitate error reporting. In conjunction with the President's 2004 call for national implementation of Electronic Medical Records (EMRs) and creation of the office of the National Coordinator for Health Information Technology, this Act should support the creation of searchable electronic databases of errors that are secure, involve low medico-legal risk, and can be analysed and used to develop systemic solutions to healthcare safety problems (Thompson and Brailer, 2004).

The huge chasm that exists between the potential and the actual quality of care delivered by the US healthcare industry appears to be consistently wide across the nation (Joseph et al., 2007; McGlynn et al., 2003). It is reasonable to state that this chasm prevails across the world. The World Health Organization (WHO) has formed an 'Alliance for Patient Safety'. According to WHO, patient safety is a basic human right.

Figure 1 portrays a patient's typical encounter with any healthcare setting. It describes three possible outcomes from the patient's point of view. Also shown are the corresponding actions that the healthcare system should take or be proactive about.

Figure 1 Patient's encounter with the healthcare system (see online version for colours)



Patients are increasingly being recognised as partners in healthcare, particularly with the advent of the patient-centred medical home movement. *They are a major source of knowledge about the state of healthcare safety*. Previous attempts to elicit error reports from patients have had limited success, due to a variety of factors, particularly the health

literacy gap. Little is known about how best to take advantage of the valuable knowledge and experience of patients and their caregivers.

We need to create a common vision that is clearly understood by patients and providers, thus creating team spirit between them. Agency for Healthcare Research and Quality (AHRQ) draws attention to this in its Patient Safety Primer.

A natural question therefore is: can visualisation provide a clear common language and a common vision of safety in the healthcare system in the USA and the World? We believe that, as the saying goes, "A picture is worth a thousand words".

Collation of reports into central databases can be useful at two levels. First, and currently the focus of most efforts, is the regional, national, or international level, which the authors shall refer to as the 'macro-system level'. These databases have the potential to receive large numbers of reports and therefore may be able to detect infrequent errors and track trends in reporting frequencies over time. In addition, since a large number of providers and patients (customers) will, it is hoped, submit data, the publication of summary statistics will not compromise the confidentiality of individual providers. In the USA, legislation will help to protect these data from medico-legal discovery.

The difficulty with this 'macro-system level' error analysis is that the generalisations derived from macro-level data might not apply (*or, be perceived by individual physicians to apply*) to the individual practices or hospital floors. The Director of the US AHRQ has emphasised that quality and safety information needs to be made useful at the point of care to patients and healthcare providers (Clancy, 2005). Similarly, the UK's House of Commons Committee of Public Accounts, in its report 'A safer place for patients: learning to improve patient safety', calls for a unified and convenient form for reporting and taxonomy that encourages feedback on solutions to *specific* patient safety incidents (House of Commons Committee of Public Accounts, 2006). Therefore, in addition to the 'macro-system level' data, individual practices/healthcare-sites and organisations need local 'micro-system level' information that is directly relevant to them and can be used internally to drive safety improvement. Such information, reported internally for quality and safety improvement purposes, potentially has more legitimacy in the eyes of local staff and clinicians in any healthcare setting.

It is important to point out that a recent (March 2010) report by the US Department of Health and Human Services Office of the Inspector General to Congress on methods for identifying adverse events in hospitals shows concern that incident reporting systems (five different screening methods) are missing the majority of events, and are unreliable. The report suggests that current hospital reporting may be unreliable as a source of information for the Patient Safety Organizations (PSOs) that were set up as a result of the Patient Safety and Quality Improvement Act of 2005. These PSOs are the entities that are registered in the USA by the federal AHRQ to receive, aggregate and analyse the adverse events reports data. The overall objective, as stated earlier, is to learn from errors and devise interventions to improve safety. The Office of the US Inspector General has recommended that AHRQ should explore for better ways of assessing the state of safety at any time and monitoring it over time.

It will be useful to be aware of the overall process of error reporting, barriers faced by reporters, and the role of leadership and safety culture (Singh et al. in this issue) on patient safety improvements. Our conceptual model for these is presented is presented in Figure 2.

Figure 2 Conceptual model for the error reporting cycle and the barriers faced by potential reporters (see online version for colours)

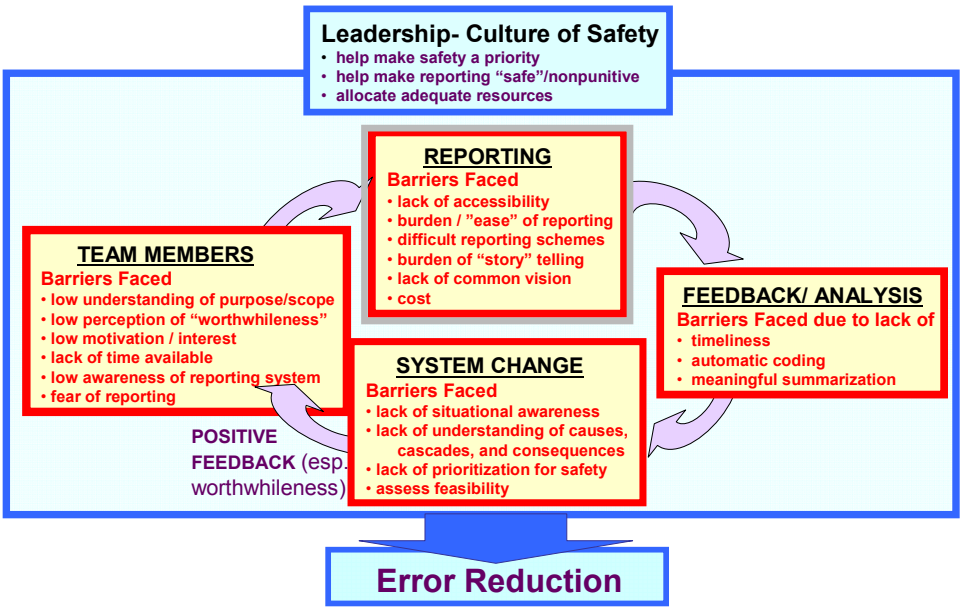
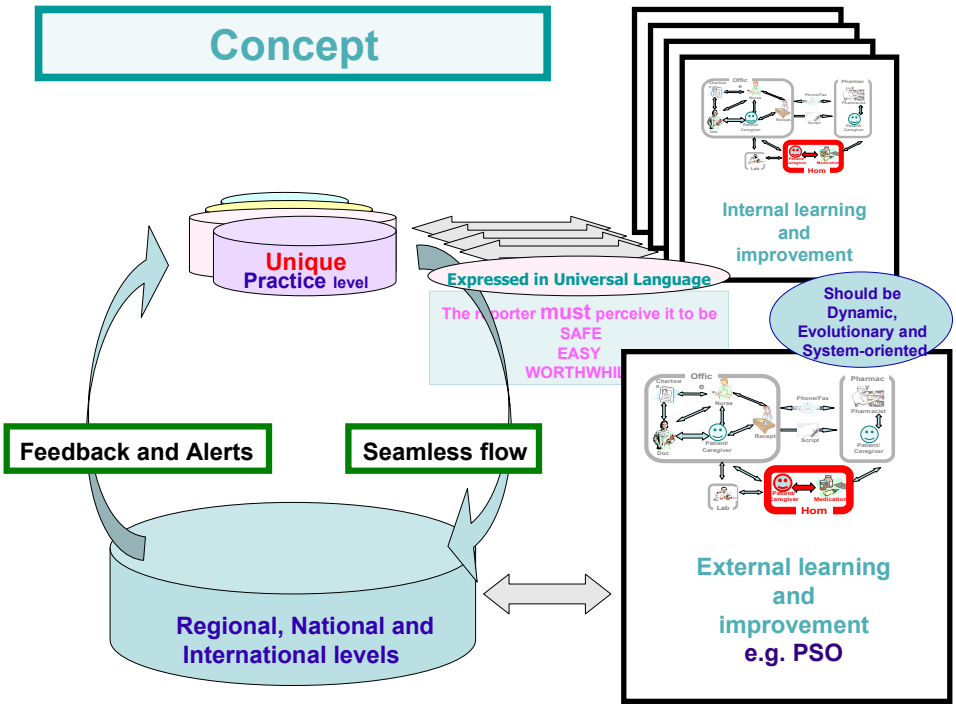


Figure 3 Overview of the web-based concept for visual taxonomy and reporting (see online version for colours)



The general purpose of our work is to develop and test a concept for visual medical error taxonomy, built on visual reporting, that can provide for both 'macro-system' and 'micro-system' level needs. Figure 3 depicts the overall concept in which error reporting at the micro-system level is used internally for safety improvement as well as being fed seamlessly to a regional, national, or international database that is used to study the epidemiology of errors and to generate alerts. The purpose of this paper is to present the concept of visual reporting.

Before presenting this concept it will be helpful to describe the framework of the error taxonomies that have to be populated by the proposed visual reports.

2 Error taxonomies

Numerous error taxonomies have been and are being developed to organise and classify error reports. The IOM's report 'Patient safety: achieving a new standard for care' [102] calls for the development of an event taxonomy. The WHO (2009) is working to establish a common international system for classification. The International Primary Care Patient Safety Taxonomy Steering Committee has set itself the important and necessary task of developing "a primary care taxonomy for patient safety, embedded in the International Classification of Primary Care (ICPC-2) and in an episode of care structure, that can operate across settings and vendors, and that maps to other standards and data structures" (Chen and Philips, 2005).

Current taxonomies are essentially alpha-numeric codes that are used to classify error data and summarise it (whether at local, regional, national and international levels) for various purposes including:

- communication of information about errors and their characteristics including causative factors, consequences, and severity (keeping in mind that error reporting alone may be insufficient for fully addressing these issues)
- estimation of frequencies and trends of various error types
- identification of needs for safety improvement.

These current taxonomies have a number of limitations:

1 The coding systems are complex and prone to ambiguity.

2 They do not readily meet the *point-of-care* needs of patients and health providers to understand, within their own unique micro-systems, the causes, cascades and consequences of the reported errors.

3 They do not fully capture the 'story'. By reducing an incident to a series of codes, the flavour of the event is lost. It is the 'story' that has the greatest potential to contribute to safety improvements (Billings, 1998; Chang et al., 2005).

4 They often differ in the way they define, count and track events, and they use different terms, data and coding methods and analysis. This makes it difficult to compare data that have been collected or coded using different taxonomies.

The US IOM (Aspden et al., 2004) states that a comprehensive National Health Information Infrastructure must provide information flow across three dimensions:

1 personal health, to support individuals in their own wellness and health decision making

2 healthcare providers, to ensure access to clinical decision support systems

3 public health, to address and track public health concerns and health education campaigns.

Items 1 and 2 correspond to the micro-system level while item 3 is at the macro-system level. Use of a consistent error taxonomy across these levels is imperative.

The imperatives for consistent error taxonomy at both micro- and macro-system levels, presents an opportunity to harness the benefits of computer visualisation. The authors' experience with visualisation so far suggests that this helps to create crosswalks across disparate taxonomies. A very important feature of visualisation is that it can help to structure and illustrate the 'story' of an error or event. The proposed visual taxonomy is coded at four main levels, corresponding to the structure of the visual models (Weingart, 2005):

- healthcare domain
- process
- sub-process
- entity/interaction.

An event can consist of one or more errors, together with causes and consequences. Each of these is coded at the above four levels.

3 Visualisation

The authors take the view that visualisation is a universal tool that furnishes a natural common 'language'. For instance, it is used effectively for international road signs. It respects and aids inductive (as against linear) perception and decision making. It can provide:

1 a fast path to fully engaging the minds of individuals and their teams *including patients*

2 insight to causes, cascades and consequences of errors

3 a common vision for teamwork, with the potential for improved outcomes,

4 aid for coping with the complexities, fragmentation and decentralisation of the healthcare system

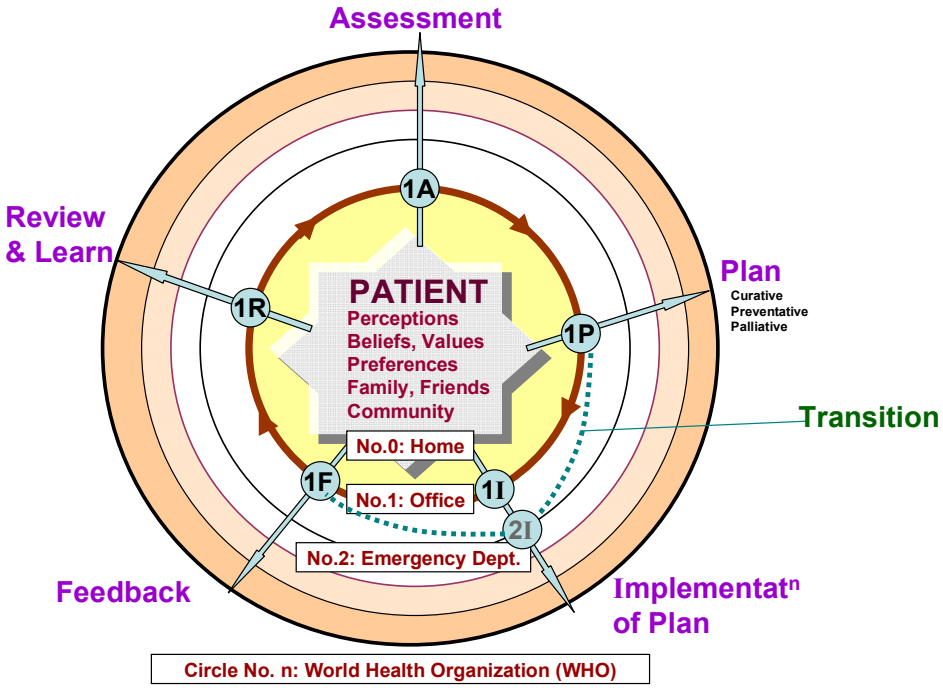
5 aid for mapping across different taxonomies and data structures (Buzan, 1991).

Applying a systems engineering/management approach, the authors have developed visual models at the macro-system and micro-system levels (Singh et al., 2007).

4 Macro-system model

The macro-system model is a high-level view (Figure 4) of the healthcare system. The processes of care are represented by the radials. These processes are recognised to occur in a cyclical fashion as shown by the clockwise progression around the circle from 'Assessment to plan to implementation, feedback, review & learn and back to assessment again' (Singh et al., 2007, 2005). These cycles of care take place in various domains that are depicted by concentric circles. The increasing sizes of the circles depict the enlarging involvement of the system, starting from the patient level (Circle No. 0) at the centre to the international health authority level (Circle No. n) on the outside. The innermost circle represents the patient in his/her own domain (i.e., home/community) and recognises that this is the place where most 'healthcare' actually occurs. International health authorities (e.g., WHO), depicted by the outermost circles, play an important role in devising public health policies that can impact management of patients at all points within the system. Office-based primary care is represented by Circle No. 1. Depending on the system under study, Circle No. 2 might represent the emergency room and No. 3 might represent the hospital inpatient setting, etc.

Figure 4 Macro-system model of healthcare (see online version for colours)



The main purpose of this macro-system model is to understand a patient's care in the context of the overall healthcare system, especially with respect to errors and opportunities for errors, including in transitions between different parts of the system.

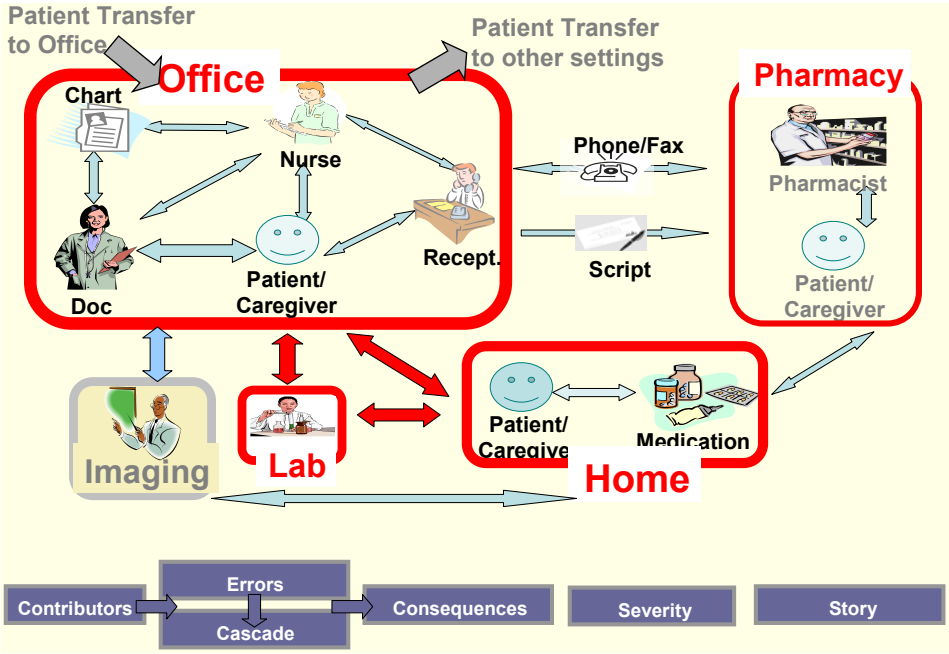
Cycles of care can occur multiple times in one setting and/or involve transitions between settings. The macro-level view aims to provide the 'big picture' so as to facilitate understanding of the processes of care in different interrelated parts of the

system and transitions between these parts, helping the user to understand interdependencies and needs for information flow.

5 Micro-system model

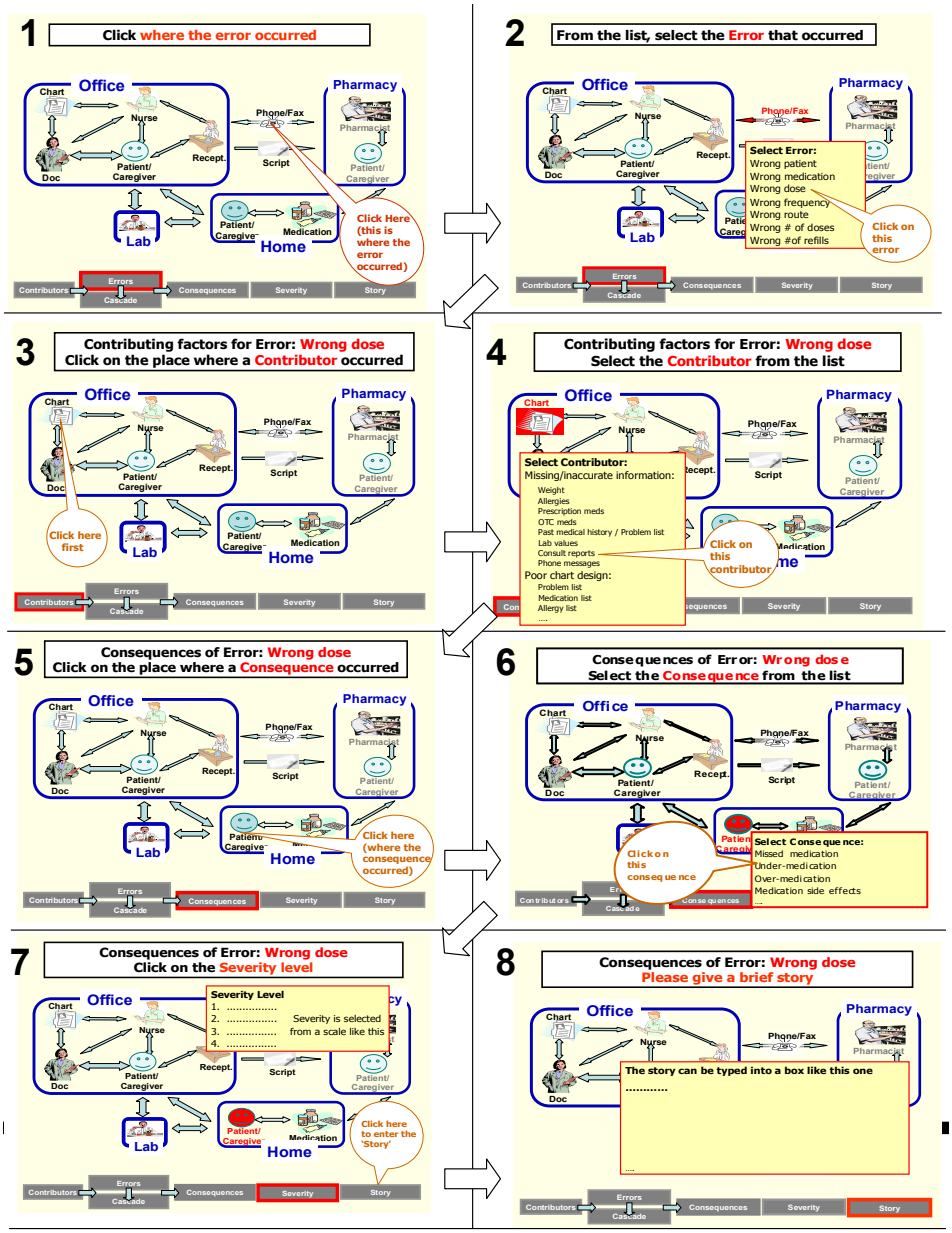
Micro-system models are close-up views of the system; each may represent one or more points within the macro-system model. For example, one may devise a micro-system model for a specific domain within the macro-system, or for a specific process within a domain. These models show how the various entities/agents in the micro-system interact. The level of detail represented in a micro-model depends on the purpose for which it is used. Figure 5 is an example of a micro-system model for medication management in ambulatory settings and shows activities in the office, pharmacy, home, laboratory, imaging/radiology facility, and third party payer, and the interactions within and between these. Each interaction is shown as an arrow. Errors or safety problems can originate at any, or at multiple points within the system.

Figure 5 Micro-system model of a primary care setting (see online version for colours)



The macro-system and micro-system diagrams are computerised and contain 'hyperlinks' that facilitate hierarchical linkage between models and can be used for dynamic data links within databases. For example, any point on the micro-system model can be linked electronically to a table containing relevant data about errors that are known to occur at that point in the system with details of frequency and consequences of these errors as well as corrective action recommended or used. These macro- and micro-system models can also provide various other functions that the authors have described elsewhere (Singh et al., 2007).

Figure 6 Example of interactive error reporting: ambulatory setting example (see online version for colours)



6 A visual error reporting tool

Figure 6 is an example of how a visual reporting tool could be used, based on the same micro-system model shown in Figure 5. To report an error, the user would first describe

the patient's demographic details and enter other information deemed appropriate, such as their job designation, circumstances in which they discovered the error, etc. Then they would commence entering details of the error using the visual interface. In this case, the error is that the primary doctor (who is reporting this error) refilled the wrong dose of a blood pressure medication by phone. The patient is a 76-year-old female with type 2 diabetes mellitus, hypertension, and coronary artery disease (CAD). She sees her primary doctor every three months and is on various appropriate medications, including Quinapril 10 mg daily for hypertension. She also sees a cardiologist annually for CAD follow-up and management. At today's visit to the primary doctor's office, the doctor notices that her blood pressure is above goal at 147/90, while it had been well controlled at previous visits (including the most recent visit three months ago). Therefore, he/she inquires as to the patient's compliance with the medication, to which the patient replies "my pressure's probably up because you cut down my medication dose last time". The doctor reviews the chart and finds no documented change in any blood pressure medication. He/she inquires further and discovers that at the patient's previous visit to the cardiologist (eight months earlier), the cardiologist had noted elevated blood pressure and increased the dose of Quinapril from 10 mg to 20 mg daily and also prescribed a 6-month supply. Then, two months ago, when the patient was running out of Quinapril, she called her primary doctor's office for a refill. The doctor reviewed the chart and instructed the nurse to phone in a prescription for Quinapril 10 mg daily, since this was the dose documented in the patient's chart. There was no report in the chart from her cardiologist. The patient had seen the primary doctor twice since the cardiology visit but apparently had not mentioned the dose change.

Panel 1 of Figure 6 shows how the doctor would indicate the location of the error, which in this case is in the communication (via telephone) between the doctor's office and the pharmacy. Next, in Panel 2, when presented with a list of possible errors in this step, the reporter picks the relevant item from the list, which in this case was 'wrong dose'. Next, the user chooses to describe the contributing factors. As mentioned earlier, one of these was that the chart did not contain any information from the cardiologist regarding the dose change. The user therefore clicks on the chart and chooses the appropriate item from the list, as shown in Panels 3 and 4. Another contributor was that the patient did not inform the primary doctor about the dosage adjustment; this can be entered in the same fashion.

Similarly, the user is prompted to indicate the location and nature of any consequences. In this case (Panels 5 and 6), the patient was under-medicated. Finally, the severity of the error can be elicited, usually on a scale, as indicated in Panel 7, and the user types a brief narrative description of the event to add any other details and help to eliminate any ambiguities (Panel 8). The various lists, hyperlinked to the entities and their interactions, are designed to help reduce emotive and cognitive biases in perceptions and reporting. This is bound to be particularly helpful to patients.

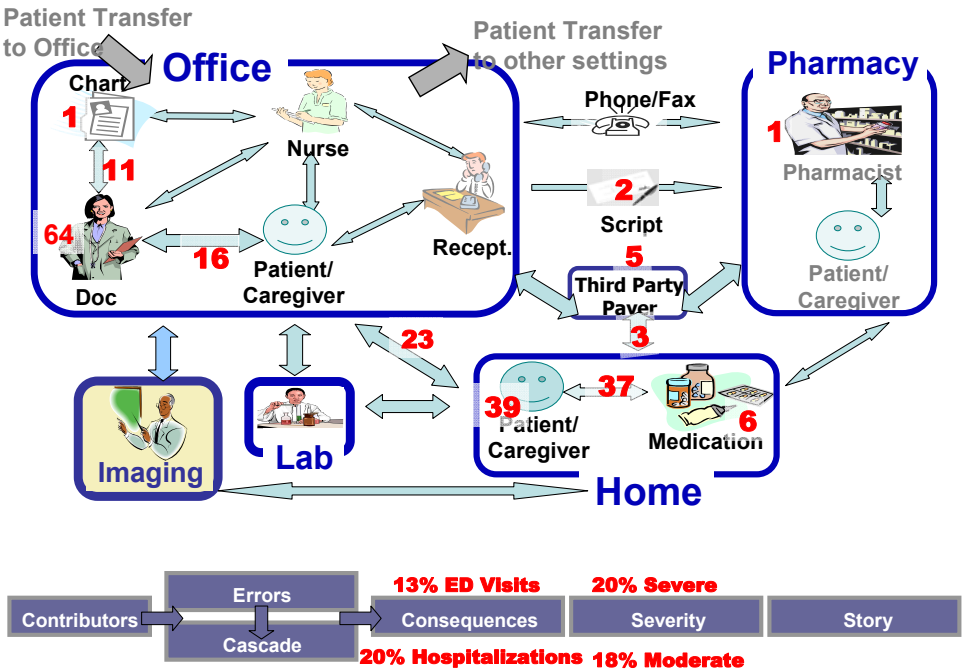
7 Discussion

Error reports can be a rich source for understanding causes, cascades and consequences of errors, in turn leading to the design of interventions for improvement. But it should be acknowledged that error reports are only the 'tip of the iceberg' since only a small fraction of errors are typically reported, and the information contained therein is limited

to what reporters perceive and are willing to share. Other methods of analysis, including failure modes and effects analysis [Singh et al. (2009a, 2009b), this issue of the journal], root cause analysis, chart review, direct observation, and others, are needed to provide a more complete assessment of risks within an organisation, Error reporting is nevertheless an important modality and should be seen as complementary to the other approaches.

The authors have proposed a novel approach, based on computerised visual models of the healthcare system, to facilitate the reporting, summarising, and dissemination of information about medical errors in healthcare. The purpose is to make information about medical errors useful both at the practice level and at the policymaking level. Figure 7 shows an example of visual mapping of errors captured in eleven primary care offices over a period of 12 months. The ability to view a macro- or micro-system diagram together with error frequency information can be valuable in helping decision makers at various levels in the healthcare system identify and prioritise areas for system improvement. Similarly, the ability to summarise a single event – including errors, contributing factors, and consequences – in a clear visual format would appear to provide some advantages when compared to a list of codes. It should be noted that in any reporting system, reports are submitted by human beings who have their own unique viewpoints and past experiences that colour their perception of incidents. For example, perceptions of contributing factors will likely vary among reporters for the same incident.

Figure 7 Example of visually compiled data (see online version for colours)



Visual modelling can help overcome this issue because the process of reporting involves looking at and interacting with system models. These remind the reporter of the processes that are in place, his/her role in them, the problems that can occur, contributors that might be present, and consequences that can occur, thereby improving situational awareness

(Craig, 2001), as well as aiding narration of the 'story'. In other words, the visual models and associated drop-down lists have the potential to help create a common vision of the system. Furthermore, the authors suggest that a visual format can facilitate information sharing with team members and other stakeholders (including patients and families) and has the potential to enhance the understanding of events, thus facilitating the development of preventive strategies. Another benefit, important from a practical perspective, is the fact that this visual reporting approach allows the user to code the error while reporting it.

This contrasts with conventional reporting systems using existing taxonomies, which require considerable time and effort to dissect written error reports and code them. Individual healthcare settings wishing to collect and understand local error data generally cannot afford the time and effort required to manually code errors using alpha-numeric taxonomies, nor are they likely to have the expertise to do so.

Further work is needed to fully 'operationalise' the concepts described here and to evaluate the usability of the visual interface and its potential benefits. In order for the process to be used across all healthcare settings and internationally, it would be necessary to create visual diagrams of other systems. The authors are beginning to create standardised icons for the whole range of entities in the various settings of the healthcare system. Figure 8 illustrates the concept. These would enable interactive creation of micro-system models (potentially by end-users) for any setting.

Figure 8 Visual work-flow model: family medicine office example (see online version for colours)

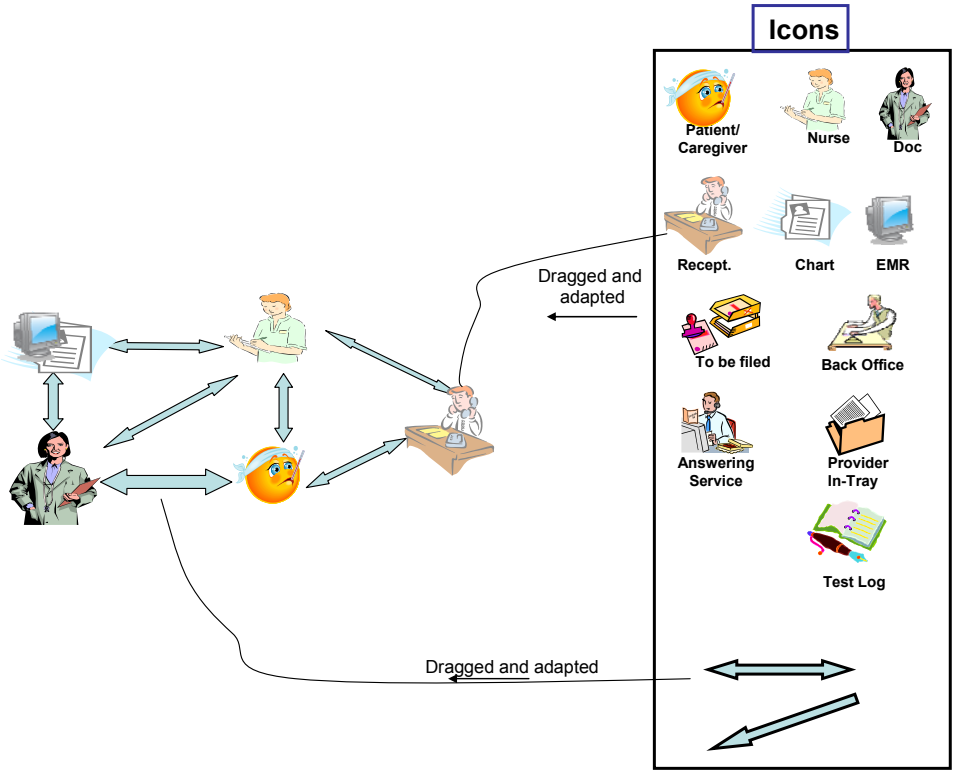
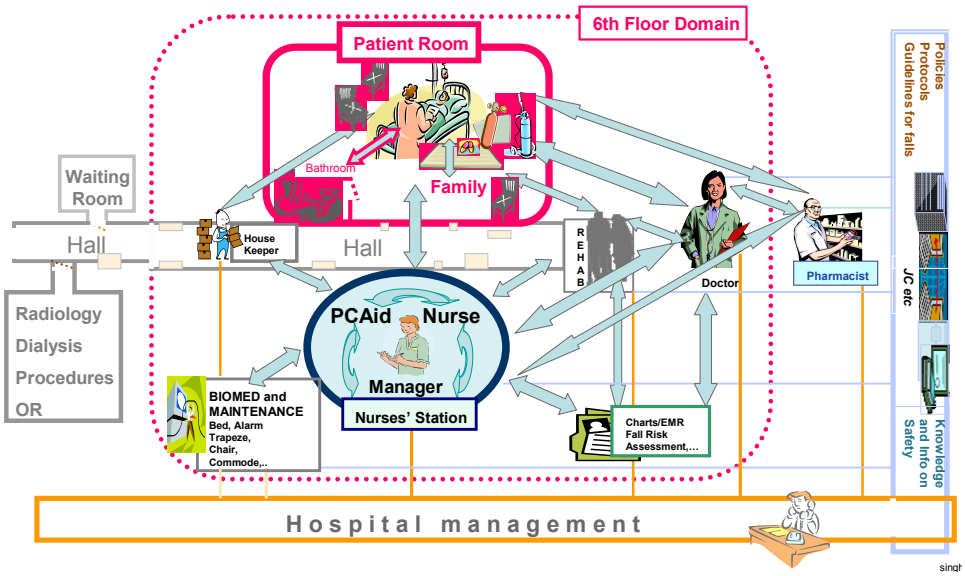
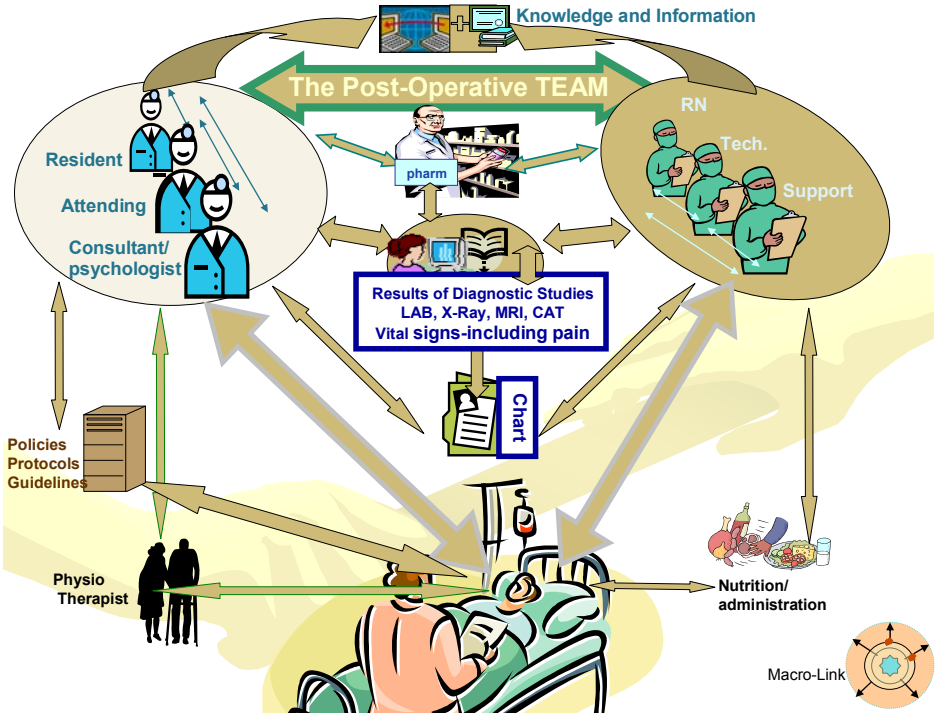


Figure 9 (a) Examples of micro-system models for falls management and (b) post operative pain management (see online version for colours)



(a)

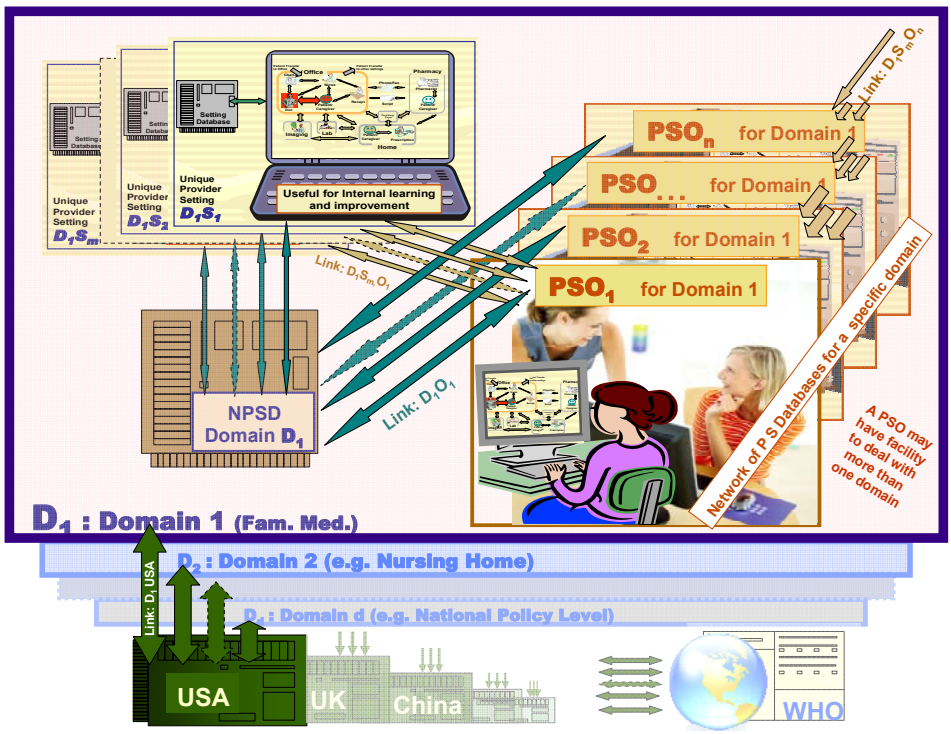


(b)

Figure 9 shows two examples of micro-system models developed for falls and postoperative pain management in hospital settings. In addition to facilitating use in a wide variety of settings, this kind of reporting tool should be accessible directly from electronic medical record systems and should be able to import patient data directly from these records. A recent study (Haller et al., 2007) in the domain of operating rooms demonstrated that integration of an incident reporting system into an electronic patient record significantly increased the number of incidents reported. A visual reporting system, aided by touch-screen technology, should increase the rates of reporting in all healthcare settings very significantly.

While tracking rates of errors over time or comparing rates among different institutions or regions are commonly perceived aims of error reporting systems, caution is needed in interpreting such data because of the problem of underreporting. According to IOM estimates, only about 5% of known errors are reported. Therefore, differences in rates of errors reported over time or among institutions do not necessarily reflect true differences in rates of errors but may merely represent differences in reporting behaviour. In the USA PSOs are being setup to receive confidential and anonymous error reports. Figure 10 portrays the model proposed by the authors to facilitate the whole process at not only healthcare-domain, regional and national levels but also at the WHO level.

Figure 10 Web-based links between micro and macro data bases of errors (see online version for colours)



It is important to point out that those errors that are reported most frequently are not necessarily the errors that occur most frequently. They are merely the ones that reporters feel more comfortable reporting (Nuckols et al., 2007). It is hoped that creating more

user-friendly and intuitive reporting tools, such as the one described here, will help increase reporting rates, and so provide more opportunities to learn. However, this needs to be done in concert with changes in organisational culture (Singh et al., 2006) that encourage reporting and learning from errors that are due to systemic problems. In other words, a shift from the prevailing culture of blame to a culture of safety, is called for. A touch-screen aided visual reporting system and taxonomy has a great potential to help this shift by creating a shared vision of the state of the healthcare system.

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Prototype Consumer Reporting System for Patient Safety

Following my approach to Dr. Clancy, I have been advised and encouraged by Dr. Munier to write to you my comments on the AHRQ proposal. Having read through the 11 attachments sent by Dr. Munier I would like to make the following comments:

(1) Despite the fact that the collection of reports from all stakeholders (especially consumers) will continue to represent, for the foreseeable future, only the tip (please see Exhibit 1) of the total burden of harm it is vital to support this mission of AHRQ.

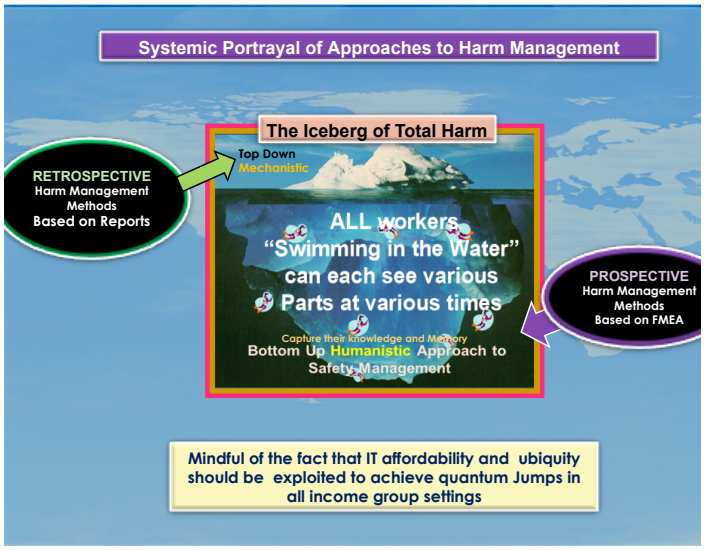
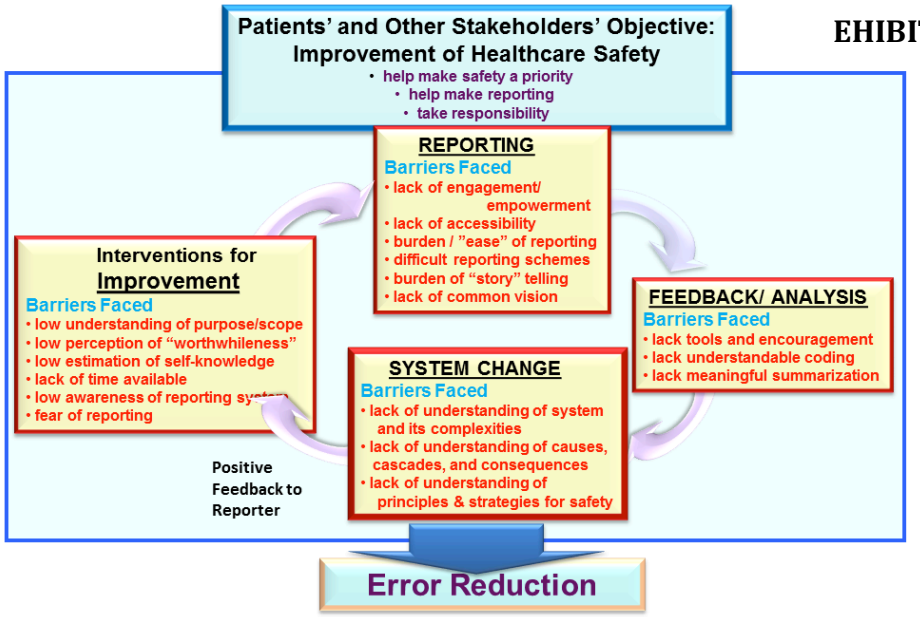


EXHIBIT 1

(2) In this mission we must recognize the role of barriers and facilitators to reporting. This is illustrated in Exhibit 2.



EHIBIT 2

(3) All the current methods of collection of reports have been found to be deficient even by the US Inspector General. This calls for an innovative approach rather than sinking more resources in the current systems if we aspire to facilitate collection of enhanced quality, utility, and clarity of *information.*

This *Information* is much more than the alpha-numeric *data* that the current methods furnish. As a matter of fact the Inspector General has recommended that AHRQ should explore better ways of assessing the state of safety at any time and monitoring it over time.

The current taxonomies, as alpha-numeric codes, have a number of limitations:

- They do not readily meet the *point-of-care* needs of patients and health providers to understand, within their own unique micro-systems, the causes and consequences of the reported errors.
- The coding systems are complex and prone to ambiguity.
- They often differ in the way they define, count and track events, and they use different terms, data and coding methods and analysis. This makes it difficult to compare data that have been collected or coded using different taxonomies.

They do not fully capture the "story." By reducing an incident to a series of codes, the flavor of the event is lost. It is the "story" that has the greatest potential to contribute to safety improvements.

(4) The consumer reporting system has to be designed to facilitate:

a. clearer perceptions of what a medical error is
b. what the cascades and consequences of errors can be
c. how to narrate the "story" of an event
d. how to make suggestions for avoiding future errors
e. removing/minimizing the fear of reporting due to emotive and cognitive biases
f. how and where to report
g. how to receive feedback for their valuable input
h. comparison between various health care settings.

My team and I have developed an innovative concept that takes advantage of a visual language. This has been published and presented at national and international conferences, including WHO wherein I am on an expert panel on patient safety, where it has been received enthusiastically. Attached is a recent paper **(I**nternational **J**ournal of **A**dvanced **I**ntelligence **P**aradigms **(IJAIP)- Volume 3, Number 1, January 2011)** for your information. I have already shared this with Drs. Clancy and Munier.

We aspire to develop and disseminate our visual system with support from and partnership with AHRQ.

(5) We take the view that visualization is a universal tool that furnishes a natural common ‘language’. For instance, it is used effectively for international road signs. It respects and aids inductive (as against linear) perception and decision making. It can provide:

1. a fast path to fully engaging the minds of individuals and their teams *including patients*
2. insight to causes, cascades and consequences of errors
3. a common vision for teamwork, with the potential for improved outcomes,
4. aid for coping with the complexities, fragmentation and decentralization of the healthcare system
5. aid for mapping across different taxonomies and data structures.

From: Lefkowitz, Doris C. (AHRQ)
To: Roemer, Marc I. (AHRQ)
Subject: FW: Patient Harm
Date: Friday, October 05, 2012 11:26:39 AM

Please send her the materials

From: Susan Chandler [mailto:schandler@mcvh-vcu.edu]
Sent: Friday, October 05, 2012 11:26 AM
To: Lefkowitz, Doris C. (AHRQ)
Subject: RE: Patient Harm

Thank you, I would be interested.

Susan
Susan Chandler, MS, RN-BC
Nurse Clinician, Ambulatory Care Clinics
VCU Health System
(804) 827-3961, pager 373-0583/6576
Fax: 827-8411, schandler@mcvh-vcu.edu

From: "Lefkowitz, Doris C. (AHRQ)" <Doris.Lefkowitz@ahrq.hhs.gov>
To: Susan Chandler <schandler@mcvh-vcu.edu>
Date: 10/05/2012 10:59 AM
Subject: RE: Patient Harm

Thank you for your comments. If you would like to review all the study materials please let me know and I will provide them

From: Susan Chandler [mailto:schandler@mcvh-vcu.edu]
Sent: Friday, October 05, 2012 10:58 AM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Patient Harm

Ms Lefkowitz,

Having just read an article a non-clinical colleague just shared with me about patient harm, I would like to share a few comments with you.

As a health care professional: We take safety seriously. It is the mission of our health system to one day be the safest hospital in America. We have educated all our employees from CEO to Environmental Services to Volunteers about safety and given them safety tools to use. As leaders, we recognize and reward publically those "caught in the act" of preventing harm. I'm proud to be part of a system that takes patient safety so seriously.

As a consumer of healthcare services, it's obvious we have a long way to go. During a recent hospitalization for my husband, despite all the safety initiatives, if I had not been for my presence to advocate for him, there could have been multiple opportunities for medical errors. From my standpoint, one of the most essential areas for us to improve is medication safety. That was demonstrated to my by the nurse administering medications to the hospitalist preparing him for discharge. If I were to do a cursory root cause analysis, I would explain it as poor communication.

I am a strong advocate of voluntary reporting systems for medical errors and near misses. Part of my responsibility as to monitor those for trends and issues for our large outpatient clinic system. On more than one occasion we have been able to recognize patterns and intervene before harm or unintended outcomes occurred. These systems may not be perfect, but they are a step in the right direction. The opportunity for consumers to have a voice is a component that is missing in this process. I encourage AHRQ to consider the possibility of adding patients who have experienced harm to our reporting systems.

Thank you,
Susan Chandler, MS, RN-BC
Nurse Clinician, Ambulatory Care Clinics
VCU Health System

(804) 827-3961, pager 373-0583/6576
Fax: 827-8411, schandler@mcvh-vcu.edu

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From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Public Comment on Proposed Information Collection
Date:	Tuesday, October 02, 2012 3:17:40 PM

From: Samuel Mahaffy [mailto:samuelmahaffy@gmail.com]
Sent: Tuesday, October 02, 2012 3:13 PM
To: Lefkowitz, Doris C. (AHRQ)
Cc: washington-advocates-for-patient-safety@googlegroups.com
Subject: Public Comment on Proposed Information Collection

To: Department of Health and Human Services
Agency for Healthcare Research and Quality

Dear AHRQ:

I write in public comment to strongly support the development of a prototype Consumer Reporting System for Patient Safety Events. I am a charter board member of the Washington Advocates for Patient Safety, a non-profit organized in the State of Washington. Our board is comprised entirely of individuals who have experienced significant harm as a result of medical error or adverse medical events. Very often these events are not reported either because the experience of the patient or their family is not solicited, much less listened to by health care providers or the medical provider does not consider themselves obligated to report the event. Collection and reporting of information from health care consumers empowers members of the public to be advocating for their own health and safety and that of the public at large. It increases accountability of providers while not placing an undue burden.

I strongly support the efforts of AHRQ to move forward with the Prototype Consumer Reporting System for Patient Safety Events.

Respectfully submitted,
Samuel Mahaffy, Executive Director
GRE Consulting Associates
samuelmahaffy@gmail.com
Charter Board Member: Washington Advocates for Patient Safety

From: yy8@u.washington.edu
To: Roemer, Marc I. (AHRQ)
Subject: Re: FW: Proposal for consumer reporting system for patient safety events
Date: Tuesday, October 02, 2012 2:22:49 PM

Marc, Thank you very much for the documents. I will read them and get my comments in.

Thanks again!

Yanling

~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

On Mon, 1 Oct 2012, Roemer, Marc I. (AHRQ) wrote:

> ++
>
> Warning text added to this message by
> UW Information Technology
> help@uw.edu
>
> ATTACHMENTS RENAMED
>
> This message came to the UW with an attached file with a
> name that ended in .zip or .exe. Because files of this
> type can automatically infect computers with a virus, the
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>
> o If the sender of the message is known to you, and you
> were expecting the message, you need simply save the
> attachment using the original name or save it as is and
> rename it back to the original name on your computer.
>
> o If the sender is not known to you, it is possible that
> the attachment contains a virus and you may simply
> delete the message.
>
> o If this message claims to be official and
> instructs you to open the attachment to get
> important information, it is likely to be fake.
> Virus writers are increasingly using sophisticated
> social engineering techniques to mislead people.
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> UW-IT never sends important information about your
> account or password in an email attachment. Instead
> you will be directed to a web page on a UW-IT site.
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> phone: 206.221.5000
>
> Warning text added to this message by
> UW Information Technology
> ++
>
> Yanling, thank you for your interest in this project "A Prototype Consumer Reporting System for
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

Patient Safety Events." I have attached all of the documentation. Please note that Supporting Statement Part B is in draft form at this time. Because the project is still under review, other documents and/or questionnaires may change as well.
>
> Marc Roemer
> Agency for Healthcare Research and Quality
> Marc.Roemer@ahrq.hhs.gov
>
>
> -----Original Message-----
> From: yy8@u.washington.edu [mailto:yy8@u.washington.edu]
> Sent: Saturday, September 29, 2012 11:45 PM
> To: Lefkowitz, Doris C. (AHRQ)
> Subject: Proposal for consumer reporting system for patient safety events
>
> Dear Ms. Lefkowitz,
>
> I am very interested in this AHRQ proposal and would like to get copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden.
>
> Thank you so much for your assistance.
>
> Sincerely,
>
> Yanling Yu
>
> washingtonadvocatesforpatientsafety.org
>

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Alert: New Task Assigned to Me and Others.
Date:	Tuesday, October 02, 2012 11:56:45 AM
Attachments:	Incoming 1448.pdf

From: Nunley, Cindy E. (AHRQ)
Sent: Tuesday, October 02, 2012 9:54 AM
To: Lefkowitz, Doris C. (AHRQ)
Cc: Cohen, Steven B. (AHRQ)
Subject: FW: Alert: New Task Assigned to Me and Others.

Doris,

Attached is letter from Congressman Bill Cassidy to Carolyn under control 1448, due 10/16. We are to provide input for CQUIPS to prepare Carolyn's response. Please copy me when you send it to Steve for review. Thanks.

Cindy

Perry, Wendy (AHRQ)

From: Migdail, Karen J. (AHRQ)
Sent: Monday, October 01, 2012 6:03 PM
To: Ginieczki, Boyce (AHRQ)
Cc: Henry, Diana (AHRQ); Clancy, Carolyn M. (AHRQ); Holland, Howard (AHRQ); Perry, Wendy (AHRQ); Zucker, Phyllis M. (AHRQ)
Subject: Fw: Congressman Bill Cassidy Letter to Dr. Clancy
Attachments: 10.1.12 - BC et al to Clancy re. medical errors.pdf

Importance: High

Fyi...

From: Henry, Diana (AHRQ)
Sent: Monday, October 01, 2012 05:58 PM
To: Clancy, Carolyn M. (AHRQ)
Cc: Migdail, Karen J. (AHRQ); Zucker, Phyllis M. (AHRQ); Holland, Howard (AHRQ); Perry, Wendy (AHRQ)
Subject: FW: Congressman Bill Cassidy Letter to Dr. Clancy

Carolyn:

I have printed out a copy and put on your desk for tomorrow. I have also forwarded to Wendy to log into the control system.

Diana

Diana Henry
Executive Assistant
Dr. Carolyn Clancy, Director
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850
PHONE: 301-427-1203
FAX: 301-427-1210
EMAIL: Diana.Henry@ahrq.hhs.gov

From: Austin, Courtney [mailto:Courtney.Austin@mail.house.gov]
Sent: Monday, October 01, 2012 10:05 AM
To: Henry, Diana (AHRQ)
Subject: Congressman Bill Cassidy Letter to Dr. Clancy

Courtney Austin
Legislative Director
Congressman Bill Cassidy, LA 06
(202) 225-3901
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FAX: (225) 929-7084

http://cassidy.house.gov
https://facebook.com/RepBillCassidy

Congress of the United States
House of Representatives
Washington, DC 20515

October 1, 2012

Dr. Carolyn Clancy
Director
Agency for Healthcare Research and Quality
United States Department of Health and Human Services
540 Gaither Rd
Suite 3000
Rockville, Maryland 20850

Dear Dr. Clancy,

The *New York Times* recently reported that the Administration is considering a proposed system developed by your agency for patients to voluntarily self-report medical errors by health care providers, including doctors, hospitals, and pharmacists to the federal government. While the goal of providing greater transparency to patients is a noble one, we have significant concerns that this proposal could undermine that goal by producing inaccurate information.

While it is important to understand the subjective patient experience of care, it would be inaccurate to use this information as an objective standard of care. Many patients do not have the medical knowledge to accurately determine when an adverse medical event occurs. If an adverse medical event does occur, there is a likelihood that the patient could mischaracterize it.

Moreover, the reporting system presented in the article could give rise to under-reporting adverse medical events in certain circumstances and over-reporting in others. Such inaccurate and incomplete data would only produce misleading information about medical provider quality.

The article indicates the questionnaire consists of very vague language. For example, it asks patients why a mistake happened and asks them to pick reasons such as "A health care provider was too busy" or "health care providers failed to work together." This does not appear to be the kind of empirical data required to get at the heart of why adverse medical events occur on a system-wide scale.

Additionally, we have concerns that such a reporting system could give rise to greater medical malpractice liability insurance costs. This could increase costs and decrease quality of health care for patients.

The article indicates that, not only did your agency share the draft questionnaire with a reporter, but also many stakeholders as well, such as the American Hospital Association, the American Academy of Orthopedic Surgeons, and Project Patient Care. We would respectfully ask that you share the draft questionnaire with Congress as well.

In addition, we would ask that you please address the following questions by October 20th, 2012:

- How exactly will this information be used by the federal government?
- Will the federal government maintain a database of this information? If so, what will be its purpose and who will have access to it?
- To what extent will the information reported in this questionnaire be made public?
- How will the federal government protect the privacy of patients and providers?
- How specifically will you ensure that the information provided cannot be used in medical malpractice litigation?

Thank you in advance for your answers to the listed questions. We look forward to working with you in the future to ensure a lower cost, better quality and a more transparent health care system.

Sincerely,

Tom Coburn, M.D. (OK)
United States Senator

John Boozman (AR)
United States Senator

Bill Cassidy, M.D. (LA-6)
United States Representative

Ron Paul, M.D. (TX-14)
United States Representative

Phil Gingrey, M.D. (GA-11)
United States Representative

Paul Broun, M.D. (GA-10)
United States Representative

John Fleming, M.D. (LA-4)
United States Representative

Phil Roe, M.D. (TN-1)
United States Representative

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Comment : A Prototype Consumer Reporting System for Patient Safety Events
Date:	Tuesday, October 02, 2012 8:43:55 AM

File with comments

From: Martha Deed [mailto:mldeed@verizon.net]
Sent: Monday, October 01, 2012 8:15 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Comment : A Prototype Consumer Reporting System for Patient Safety Events

Martha L. Deed, PhD
1037 Sweeney Street
North Tonawanda, NY 14120

mldeed@verizon.net

Dear Doris Lefkowitz--

Thank you for this opportunity to respond to this proposal (Federal Register, September 10, 2012, 55475 ff).

I am a Psychologist (Retired), licensed in New York State, who has participated in research under federal, state, and private foundation grants in the area of legislative and justice responses to Family Violence. I became active in the patient safety field because five close family members have developed HAIs since 2001: Father died from MRSA in 2001. Mother died of multiple infections acquired in a nursing home and hospital in 2008. Both lived in Nyack, New York. A brother developed hospital-acquired MRSA sepsis in 2007 in Connecticut. He survived with no ongoing cardiac damage. My uncle died of hospital-acquired MRSA in Oklahoma, 2010. My daughter (and only biological child) died of multiple hospital-acquired infections and an undiagnosed spinal infection in 2009 in Williamsville, NY.

My family's experience informs me that patient safety issues are widespread, have been widespread for more than a decade, and are not adequately addressed by current efforts to collect data from providers and to develop provider-centered measures for preventing patient safety errors as defined by CMS.

You ask for comment on

(a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility

I agree that current methods of patient safety data collection are fundamentally-flawed. They depend upon voluntary submission of adverse events by providers who perceive that their adverse event reports could lead to liability issues, economic loss, and/or competitive disadvantage should the information become public. In addition, such reports could result in reimbursement penalties by CMS.

The result is that self-reporting by providers is likely weighted in the direction of significant under-reporting.
(See, for example, http://www.the-hospitalist.org/details/article/2360341/Most_Adverse_Events_at_Hospitals_Still_Go_Unreported.html)

Although a few states include mandatory reporting for some adverse events, state regulation does not appear to be consistent throughout the country. The reporting requirements, including mandatory reporting requirements, are further handicapped by funding limitations to audit the reports. (See for example, https://oig.hhs.gov/oei/reports/oei-06-09-00360.pdf)

My family's experience, while anecdotal, suggests that the above concerns are well-founded. When I reported my daughter's MRSA infection to the NYS health department, an investigator interviewed the hospital's designated patient safety officer. The PSO told the investigator that my daughter entered the ICU already positive for MRSA. That statement was contradicted by the hospital's medical record for my daughter which showed that my daughter was cultured (blood, sputum, and urine) for MRSA upon reaching the ER. All of those test results were negative. The PSO also responded to an inquiry as to whether there was an unusually high incidence of MRSA in the ICU in October-November 2009 -- by saying No (DOH report #10-06-322, pp. 6-7). But in 2011, the hospital made reference to the high incidence of HAIs in the hospital during late 2009, stating that levels were now significantly reduced ("Roswell Park and Kaleida say bloodstream infections ar down," The Buffalo News, June 20, 2011).

Such incidents render provider-based adverse events reporting virtually useless. Lesson learned: You cannot trust providers to report incidents that go against their own self-interest.

The practical utility of collecting patient safety information from consumers could add to the accuracy of current estimates of frequency and impact of these incidents on individuals and families, but only if the questions asked, manner of collection, and methods of working with and disseminating the consumer information is adequate. (See my response to c below.)

(b) Estimates of burden. No comment.

(c) ways to enhance the quality, utility, and clarity of the information to be collected

First, I think the utility of the patient reports will depend greatly on how the information is collected, how it is interpreted, and how well the public is informed about the results.

I realize that you are proposing a pilot project and not a final project with the most rigorous design. However, voluntary submission of reports is not going to get you very far if you want to know what sorts of adverse events are occurring and how often they are occurring. To draw those conclusions, you need a well-defined sample of respondents. Using kiosks does not fulfill that very basic condition. I strongly urge that the pilot study incorporate standard sample components, i.e. a well-defined denominator (all or a stated proportion of randomly selected patients) of whom a determined sample receive questionnaires -- and then a comparison within those populations between responders and non-responders to test the strength of the questionnaire findings.

An alternative approach, if you contemplate using a kiosk approach after the pilot study, would be to perform both a kiosk and a defined sample distribution in some small geographic area (matched on major variables) and then compare the results in terms of frequency and types of patient safety adverse events reported by both groups. If the kiosk approach is found to be comparable to the random sample distribution approach, I would feel better about what the kiosks reveal in terms of significance and reliability. I suspect, however, the results between the two approaches would be quite different.

I have followed the patient satisfaction survey approach fairly closely. I think that approach is truly making a contribution both to hospitals' awareness of what they need to do to improve patient satisfaction and in terms of patients making hospital choices based on the patient satisfaction reports

as disseminated on Health Compare. So, I hope this is where the proposed studies are headed.

If the patient safety surveys are not distributed via a well-defined sample and if the results are not made easily accessible to the public, then the project may not be worth undertaking.

Second, your proposal to submit a subset of patient safety reports to the providers' patient safety officer is particularly questionable. In my own family, we did not report patient safety issues because my daughter believed (and I am sure she was correct) she would experience retaliation and would find it more difficult to find the best care available in our area if she became identified as someone who complains.

For a patient to submit a report to you and then for you to pass that report back to the provider's patient safety officer simply amplifies the retaliation issue. Furthermore, in my experience (which is limited, of course, but see above), I have some doubt whether the patient safety officer would shed light on the issue.

Third, full public disclosure of the patient safety results is essential for improved patient safety. The current research plan will not allow for comparisons among hospitals, and that point needs to be made very clear. But even in the pilot study, it would be important to let the public know what sorts of adverse events are being reported and where the reports are coming from. "Where" needs to be exact -- not just "WNY hospital" which undercuts trust in all hospitals in the region, but precisely which hospitals.

Once the patient safety reports are solicited the same way (or functionally with the same systematic approach) as the patient satisfaction surveys, then the results should be made available on Hospital Compare. But in the preliminary and pilot phase, the results can still be made public, but not as part of a large database. They can be made public through the pilot study research report, and that report should be made widely available on the web as well as publicized to print media via news releases.

(d) ways to minimize the burden of the collection of information upon the respondents

(I am focusing primarily on the providers' involvement with this project.)

In the data collection methods laid out in the proposed consumer reporting system, it appears that the greatest burden might fall, not on consumer respondents but on the providers AHRQ contacts as a result of the consumer reports. Yet, as indicated earlier, the current plan appears inadequate because it places undue vulnerability on the patient responders without appreciably enhancing the strength of their reports. Reasons for this design weakness include a perceived reluctance, backed by earlier research, for providers to report adverse events. Going back to a provider with a patient-generated adverse event report in hand which potentially places the provider in a "gotcha" embarrassing and potentially vulnerable position with a regulatory agency could motivate retaliation against the consumer reporter.

Yet, comparison of consumer and provider adverse event reporting is necessary to improving patient safety. Therefore, it is critical to develop a data collection plan that will protect reporting consumers, will provide the information needed to determine whether the provider has revealed the adverse event, and will enable the researchers to determine whether the adverse event actually occurred. Consumer identity protection needs to be balanced against making undue demands on providers to locate and provide records. And -- privacy regulations must be adhered to as well.

The following modification might meet all three conditions:

What could be done, but would take more work and consequently require more funding, is to create a request for adverse incidence reports from providers that would include the consumers who have

made a report along with a few records from patients who have not made reports but whose hospital course included similarities to the participant patient. This might involve something along the following lines: You have a report from patient X who was admitted to the cardiac unit of hospital A on a particular date. You could request all incident reports for patients admitted to the cardiac unit at hospital A on that date. To further reduce the volume -- you could further define the request to include shared demographic characteristics, e.g. if the adverse event was a fall and the patient was a woman -- all incidence reports of women falling who were admitted on such and so a day, etc. The identifiers could be medical record number or birth date -- or some other piece of information that could be included in the patients' report to you that would also be on the information submitted by the provider.

The principle here would be to determine whether an adverse event report was filed for the consumer participant as well as for other patients who might have experienced a similar incident. By requesting all reports that fit a particular set of circumstances, the consumer is protected and the researchers obtain necessary data.

You could leave the non-respondent reports unexamined, so for the researchers, the extra time would be spent only to find the relevant report. But for the provider, providing those reports might add to the time involved in participation. You could guard against laying undue burdens on already overtaxed staff by defining the reports search as stringently as possible so that you might get 3 reports, not 20, that meet the conditions set out.

Comments regarding the packet of materials entitled "Consumer Reporting System for Patient Safety"

I requested and have now received copies of the CRSP documents. (Limiting my remarks to substantive issues.)

Attachment G Proposed flyer -- What does ECRI stand for? I don't think many people will be familiar with ECRI. That confuses your message.
Attachment A -- Web pages. Good except for the reference to writing a "big report" -- which struck me as very condescending. ECRI problem also
Attachment B -- Intake Reporting Form. Very good. Elicits the desired information in a clear manner.
Attachment C-- FAQs: ECRI problem. Risks of Participating? I think something needs to be said about how patients who permit contact with their health care providers will be protected from retaliation -- and whether there is a way for the researchers to track possible retaliation. Limiting the questionnaire for use only on Internet Explorer is a genuine limitation, which will cause some potential participants not to respond. Many internet users (including me) have long since stopped using IE because of security concerns. Many of us donot have IE installed on our computers any longer. Most often used browsers appear to be Mozilla, Chrome, and Opera. Bing is less desirable because of Google's propensity for collecting user data. So, you have created a barrier here. Furthermore, limiting the ability to print out the questionnaire with the participant's answers only if the participant has an Adobe file creater is likewise not a good plan. Most people do not have Adobe creation software, and there are costs in obtaining the software. Much better to be able to print using the browser's print utility. If you insist on a pdf file creator, you might consider providing information on an open source software package if one is available.
Attachment D -- Good script. I do think there will be confusion because while the promise is to maintain patient privacy, there is also a request to pass reports on to the patients' caretakers -- and this would almost certainly destroy privacy. I also think that if the report is not made available to the general public, it may limit patient participation.
Attachment E -- Intake reporting form. Good.
Attachment F -- Telephone follow-up. I would alter the script if the interviewer reaches someone other than the respondent. I think that all references to patient safety should be omitted and the

caller merely state that they are calling in regard to a research question at (and name the entity). I can think of many instances where other members of the responder's household would actually object to participation in this research. Thus I believe people's participation in the research should be kept confidential from everyone, including members of the participant's household. I consider the current script to be a genuine breach of confidentiality.
Attachment H -- Matching consumer patient safety report with the consumer's health care provider -- very important questions. But -- I don't see how it is safe to ask such questions about an identified patient. (See my comments above.)
Supporting Statement, Part A -- convenience sample well-explained. Care with conducting telephone interviews, e.g. making sure subject is in a space where they will not be overheard is good. But more care (see above) needs to be made not to reveal subject's partiicpation to household members. Not clear how report will be distributed and how complete public access to results will be. I consider public disclosure to be an essential element.
Supporting Statement, Part B -- Good that the flyer will be distributed with hospital satisfaction surveys. That should improve the quality of the convenience sample. Eventually, once the final project is under way, I hope that the questionnaire itself will be distributed with the patient satisfaction surveys.

Conclusion

Often, public policy personnel and medical economists assume that health care is a free market commodity. In fact, it is not a free market enterprise, but one in which patient choices are extremely limited. This is especially true for people who live in rural areas where there may be only one hospital or in regions such as mine where a single hospital system controls nearly half of the available hospital beds. Choice is also limited by conditions imposed by the medical insurer (HMOs, networks, etc.). Hospital choice limitations can happen even in a large urban community like NYC if one requires an ambulance and the EMTs have to take the patient to the nearest hospital. That "nearest hospital" may have a poorer record for outcomes for that patient's illness than a hospital only a mile away from the EMT's choice.

It is a matter of life and death to collect as much patient safety information as possible from as many sources that researchers can reach to challenge deficient hospitals to improve and to inform the public so that families can protect their loved ones from providers whose outcomes are below those achieved by other providers within their locality.

The AHRQ proposed research promises to aid both hospitals and the public in significantly improved patient safety, but only if the research is conducted in a rigorous manner so that the reports elicited have statistical weight, and only if the results are made accessible to the public. Currently collected patient satisfaction surveys provide an important model both for collection methods and public accessibility through Hospital Compare.

Again, thank you for the opportunity to comment on this important and promising project. It is long overdue.

Martha Deed, PhD
Psychologist (Ret) and Patient Safety Advocate
Submitted via E-mail, October 1, 2012

From: Lefkowitz, Doris C. (AHRQ)
To: Roemer, Marc I. (AHRQ)
Subject: FW: Medical Patient harm
Date: Monday, October 01, 2012 8:53:54 AM

Just file this with the other comments

From: georgendout@yahoo.com [mailto:georgendout@yahoo.com]
Sent: Monday, October 01, 2012 3:17 AM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Re: Medical Patient harm

Dear, Ms. Lefkowitz,
Thank you for the update. I do hope the VA is not overlooked. The way the system is set up it is self regulating, and protecting which is never beneficial to patients rights.
Regards

George Mc Grath

From: "Lefkowitz, Doris C. (AHRQ)" <Doris.Lefkowitz@ahrq.hhs.gov>
To: "georgendout@yahoo.com" <georgendout@yahoo.com>
Sent: Wednesday, September 26, 2012 10:20 AM
Subject: RE: Medical Patient harm

Dear Mr. McGrath,

As of this time the specific hospitals to be included in the pretest of the patient safety program have not been determined, but VA hospitals have not been excluded.

Sincerely,

Doris Lefkowitz
Reports Clearance Officer

From: georgendout@yahoo.com [georgendout@yahoo.com]
Sent: Wednesday, September 26, 2012 12:44 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Medical Patient harm

I am a United States disabled veteran who has suffered harm by Doctors in the VA system, and as you may know we have no Constitutional rights to protect us. Would the VA also be required to report any patient harm under any proposed patient safety program being considered?
I thought it important to ask this question and would appreciate a reply.
Regards

George Mc Grath
georgendout@yahoo.com
702-736-1240

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Medical error reporting
Date:	Friday, September 28, 2012 8:56:48 AM

-----Original Message-----
From: Harold [mailto:harold599@gmail.com]
Sent: Thursday, September 27, 2012 9:00 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Medical error reporting

Dear Ms Lefkowitz,

I would like to share my view on medical error reporting.

I very much believe that errors need to be reported from all medical providers. Too many people come out of medical care injured or in worse condition than when they went in for treatment. This is necessary in both hospitals and private practice.

There are some elements which need to be included in any system.

The practitioner (or someone responsible for them) must be able to respond with comments about the incident. If such comments are to be allowed, and if any of them are reviewed by an independent expert, the determination of that expert needs to be attached to the incident case transcription. The response process should include a right for the provider at fault to ask for a formal review and have that information included in the visible database.

It is also essential that this information be available to the population. Previous attempts to provide intelligent feedback on physicians has been fought with great vigor and significant success. There needs to be more tools for a person to knowledgeably select care givers. Both individual providers and institutions and businesses.

Given that some studies determined error rates at odds with reported errors using treatment codes in hospital records, I have to wonder if insurance claims would contain the necessary information to do the same analysis. A simple program, but a lot of computer power, could extract and summarize this information. Likewise insurance companies and the VA.

Respectfully,
Harold Harrington

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: centralized reporting system
Date:	Friday, September 28, 2012 8:56:06 AM

From: Kathy Grover [mailto:kathygrover@gmail.com]
Sent: Friday, September 28, 2012 2:20 AM
To: Lefkowitz, Doris C. (AHRQ)
Subject: centralized reporting system

We are in desperate need of a centralized reporting system for medical errors and a few other things too, such as a good centralized way to report drug size effects that doctors ignore. But right now, just addressing the issue of a centralized reporting system for medical errors -- we need that pronto.

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Patients reporting medical errors
Date:	Thursday, September 27, 2012 11:06:12 AM

We can just file this one too

From: Beverly Botchlet [mailto:beverlybotchlet@att.net]
Sent: Thursday, September 27, 2012 11:04 AM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Patients reporting medical errors

Doris,

I recently read the article on ProPublica.org regarding the issue of patients reporting medical errors, or better yet, not reporting medical errors. I appreciate the offer in this article to email you comments. So thank you for that.

For the last 29 years I have been a Legal Nurse Consultant. I review medical records for actual or potential medical malpractice or nursing negligence legal cases. So I know the ultimate end of the spectrum of disgruntled patients or families of patients. When a patient becomes the victim of wrongdoing within the healthcare system, they want/need a recourse. It appears to me that the legal system is the last, or rather should be the last, resort. But it often times is the first and sometimes the only recourse.

There has to be a system in place that is an avenue for these people to contact BEFORE or instead of seeking legal counsel. There are a variety of scenarios we could talk about all the way from not being treated kindly to actual injury or even death. But at some point, any wronged person will start to feel they need answers and some will feel they need justification. An avenue, a system or whatever you want to call it, could be a possible answer or outlet. Short of either having that person be resentful for the rest of their lives or for them to turn to the legal system, there needs to be a patient advocate group available to them from within the healthcare facility where they experienced an untoward event. Every healthcare institution should feel this as an obligation. Healthcare facilities can and ethically should offer a way that the patient or patient's family feels is an approachable way to begin their catharsis. That just seems reasonable. And one of the possible outcomes could be a decrease in the number of lawsuits we see filed each year.

Thanks again for this opportunity.

Respectfully,

Beverly Botchlet, RN, MS
Discovery, Inc.
16116 Pointe Oak Circle
Edmond, OK 73013
405-285-9474

beverlybotchlet@att.net

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: comment on AHRQ for reporting adverse reactions
Date:	Thursday, September 27, 2012 9:35:26 AM

From: Kcls1@aol.com [mailto:Kcls1@aol.com]
Sent: Thursday, September 27, 2012 7:04 AM
To: Lefkowitz, Doris C. (AHRQ)
Subject: comment on AHRQ for reporting adverse reactions

Dear Ms Lefkoitz, HHS,
Regarding the proposal for AHRQ to handle the reporting of adverse reactions from the public, I am concerned that it would take valuable information away from MedWatch. The MedWatch phone number for adverse reaction reporting is mandated to be supplied to the consumer by the pharmacy with every new prescription, so an additional reporting group will be confusing to the consumer. There should be just one group for collected adverse reaction information; fractionated collection of adverse reaction data for study does not serve public safety in the goal of practicing Evidence-based medicine.
Sincerely,
Katherine Suskevich RPh
2213 Edgar Rd
Point Pleasant NJ 08742

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Why patients don"t report medical errors
Date:	Thursday, September 27, 2012 9:35:00 AM

From: Mary Spelmanis [mailto:mspelman@fdltd.com]
Sent: Thursday, September 27, 2012 9:26 AM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Why patients don't report medical errors

- If they are in a facility, they are afraid they will be retaliated against and their care will be compromised or they will be deliberately harmed.
- Once they are past the event, they either are too busy dealing with the medical consequences or just want to move on with their lives.

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Comment period
Date:	Wednesday, September 26, 2012 5:06:32 PM

From: Borders, Ann [aborders@cumminsbhs.org]
Sent: Wednesday, September 26, 2012 5:05 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Comment period

I fully support the concept of patient reporting to a central agency on patient harm. I am wondering if behavioral health will be included. I would recommend it. Thank you.

Ann Borders
President and CEO
Cummins Behavioral Health Systems, Inc.
5101 East US 36, Suite 101
Avon, IN 46123
Phone 317-745-9564
FAX 317-745-9569

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Patient Harm Information
Date:	Wednesday, September 26, 2012 3:39:16 PM
Importance:	High

From: Betty Hebert [bhebert@coldwellbankerone.com]
Sent: Wednesday, September 26, 2012 3:14 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Patient Harm Information

1. should be gathered in standardized way
2. should be administered by entity other than medical provider or insurance co.
3. should be made public
4. should be user friendly
5. patient must be exempt from legal retaliation

Betty Hebert, CRP
Director
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bhebert@coldwellbankerone.com
CELL: 225-788-4232

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: reporting medical mishaps
Date:	Wednesday, September 26, 2012 2:49:11 PM

From: Lollis, Kathleen [KLollis@greenvillecounty.org]
Sent: Wednesday, September 26, 2012 1:59 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: reporting medical mishaps

I think there should be a standardized survey with routine questions. But I also think there should be a space for detailed explanations of complaints or even "kudos". I think a lot of patients are concerned about repercussions in their care with said physician or facility.
I previously worked in a physicians office for 12 years, and I would welcome criticism as a way to improve our services, and to be patient & family informative and friendly. In today's society though with the "I can sue you for whatever" attitude, I can understand the medical field and the patient concern about having complaints filed or filing the complaints. Surely there must be a way to have the survey completed with truthful facts, yet protect those complaining as well as correcting the complaints.

Kathy Lollis
Property Tax Specialist
Greenville County Real Property Services
Business Registration
301 University Ridge, Suite 1000
Greenville, SC 29601
(864) 467-7313 phone
(864) 467-7440 fax
Email: klollis@greenvillecounty.org

Don't put your thoughts toward what might have been, put your energy into what is possible.

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: medical harm survey
Date:	Wednesday, September 26, 2012 2:48:45 PM

From: Cartwright-Kerns [netsinker@windstream.net]
Sent: Wednesday, September 26, 2012 2:26 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: medical harm survey

Hello
I really don't see what a survey of medical harm is going to do for the patient. If the patient is severely affected they cannot fill out this form. Family members are likely to be too traumatized to think straight and fill out the survey. What about repercussions from the hospital or it's staff? The first thought would be that the patient is a troublemaker. The next step for them is easy: tell the patient that there is nothing more to do for them and discharge them. This way they can hope that the patient dies or push the problem off onto someone else.
What about something with teeth? Give the patient and family hope that something like this will not happen to another person. Please don't ask me to fill out a form at a time when I may no longer be able to hold a pencil.

Marilyn Kerns
netsinker@windstream.net

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Comments about Developing a Harm Reporting System
Date:	Wednesday, September 26, 2012 2:48:22 PM

From: Mary Kleinman [mkleinm@luc.edu]
Sent: Wednesday, September 26, 2012 2:14 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Comments about Developing a Harm Reporting System

Dear Ms. Lefkowitz,

I read about the plan to develop a harm reporting system in an NBC article online. I am a doctoral student at Loyola University Chicago, with a focus on medical sociology. My comments are based on observations and analysis of the care my father received while in a nursing home in Ohio, as well as other care he and my mother received over the years. I believe that there are many barriers to reporting errors, which a standardized reporting system might begin to address. In addition to developing a system of patient reporting, I would urge you to include input from family members.

Different types of assessment tools or systems would need to be developed for patients undergoing care for acute problems, chronic problems, and those who are institutionalized. On a basic level, patients and relevant family members could be asked to check off on a list if their encounters with different providers (physician, nurse, aid, other personnel) resulted in harm, as well as if the encounters resulted in distress. The reason to ask about distress is that while there might have been actual harm, the patient/family might not understand the specific nature of the harm and thus be unable to articulate it. There could also be space for additional comments. This basic type of survey could be repeated periodically for those who are institutionalized. As data were obtained from an initial reporting system, additional reporting measures could be implemented in the future. The system could be piloted on a small scale, refined, and then implemented more broadly.

Individuals who are in nursing homes or institutionalized in another type of health facility are the most likely to be subject to medical errors just because they have more encounters with healthcare personnel. I will provide one example of a medical error experienced by my father, and discuss why this was not reported. In approximately April 2011, one of my family members inadvertently learned that my father's roommate in the nursing home had C-diff. My father recently had oral surgery, and was immuno-compromised. I did a little research about this disease, and spoke with the director of nursing about my concerns, not only for my father's health, but also for the welfare of their staff and other residents. The director of nursing was dismissive of my concerns. I then researched the approach taken by other healthcare organizations in the area (e.g. The Cleveland Clinic) to C-diff patients, and learned that they isolated such patients. I also reviewed the Ohio Department of Public Health recommendations, and it seemed that while isolation was not mandated, it was strongly recommended because it was the prudent course of action. In subsequent discussions with the nursing director, she did not appear to understand the airborne nature of C-diff, and that normal antiseptic procedures were inadequate. I finally requested that my father be moved from that room, and he was. After my father was moved, other nursing staff told him that C-diff was not harmful, which I know to be false. I truly believe that there was a general lack of understanding about C-diff in this particular nursing home, resulting in care that could potentially cause a great deal of harm.

I did not report this incident for a number of reasons. I was not sure if this was a reportable offense. I did not know to whom it could be reported. Even if I could have reported it, I would have been concerned about possible retaliatory actions toward my father. His stay at this nursing home was covered by Medicaid and his Social Security, so there were not other realistic options for placement at another facility. Thus, he was dependent on his caretakers at this facility. He was not able to report this himself because he had a language barrier.

Given the extent to which patients and families depend on specific healthcare providers (especially in smaller communities), and given that there may be personal relationships with these individuals, it makes the reporting of errors challenging and less likely. However, it seems that at a minimum, when state or federal funds are used to pay for care, it is reasonable to expect some level of monitoring of the quality of care. A harm reporting system will create mountains of data, and as the system is developed, consideration must also be given to the structuring, storage, and analysis of this data, as well as what actions will be taken in cases of egregious or ongoing errors.

Thank you for the opportunity to provide my initial thoughts about the proposed project.

Regards,
Mary Kleinman

Mary Kleinman, MA
Loyola University Chicago
Center for Urban Research and Learning
6430 N. Kenmore Ave.
Chicago, IL 60626
(773) 508-8556
(773) 508-8510 (Fax)

From:	Lefkowitz, Doris C. (AHRQ)
To:	Roemer, Marc I. (AHRQ)
Subject:	FW: Comments about Developing a Harm Reporting System
Date:	Wednesday, September 26, 2012 2:48:22 PM

From: Mary Kleinman [mkleinm@luc.edu]
Sent: Wednesday, September 26, 2012 2:14 PM
To: Lefkowitz, Doris C. (AHRQ)
Subject: Comments about Developing a Harm Reporting System

Dear Ms. Lefkowitz,

I read about the plan to develop a harm reporting system in an NBC article online. I am a doctoral student at Loyola University Chicago, with a focus on medical sociology. My comments are based on observations and analysis of the care my father received while in a nursing home in Ohio, as well as other care he and my mother received over the years. I believe that there are many barriers to reporting errors, which a standardized reporting system might begin to address. In addition to developing a system of patient reporting, I would urge you to include input from family members.

Different types of assessment tools or systems would need to be developed for patients undergoing care for acute problems, chronic problems, and those who are institutionalized. On a basic level, patients and relevant family members could be asked to check off on a list if their encounters with different providers (physician, nurse, aid, other personnel) resulted in harm, as well as if the encounters resulted in distress. The reason to ask about distress is that while there might have been actual harm, the patient/family might not understand the specific nature of the harm and thus be unable to articulate it. There could also be space for additional comments. This basic type of survey could be repeated periodically for those who are institutionalized. As data were obtained from an initial reporting system, additional reporting measures could be implemented in the future. The system could be piloted on a small scale, refined, and then implemented more broadly.

Individuals who are in nursing homes or institutionalized in another type of health facility are the most likely to be subject to medical errors just because they have more encounters with healthcare personnel. I will provide one example of a medical error experienced by my father, and discuss why this was not reported. In approximately April 2011, one of my family members inadvertently learned that my father's roommate in the nursing home had C-diff. My father recently had oral surgery, and was immuno-compromised. I did a little research about this disease, and spoke with the director of nursing about my concerns, not only for my father's health, but also for the welfare of their staff and other residents. The director of nursing was dismissive of my concerns. I then researched the approach taken by other healthcare organizations in the area (e.g. The Cleveland Clinic) to C-diff patients, and learned that they isolated such patients. I also reviewed the Ohio Department of Public Health recommendations, and it seemed that while isolation was not mandated, it was strongly recommended because it was the prudent course of action. In subsequent discussions with the nursing director, she did not appear to understand the airborne nature of C-diff, and that normal antiseptic procedures were inadequate. I finally requested that my father be moved from that room, and he was. After my father was moved, other nursing staff told him that C-diff was not harmful, which I know to be false. I truly believe that there was a general lack of understanding about C-diff in this particular nursing home, resulting in care that could potentially cause a great deal of harm.

I did not report this incident for a number of reasons. I was not sure if this was a reportable offense. I did not know to whom it could be reported. Even if I could have reported it, I would have been concerned about possible retaliatory actions toward my father. His stay at this nursing home was covered by Medicaid and his Social Security, so there were not other realistic options for placement at another facility. Thus, he was dependent on his caretakers at this facility. He was not able to report this himself because he had a language barrier.

Given the extent to which patients and families depend on specific healthcare providers (especially in smaller communities), and given that there may be personal relationships with these individuals, it makes the reporting of errors challenging and less likely. However, it seems that at a minimum, when state or federal funds are used to pay for care, it is reasonable to expect some level of monitoring of the quality of care. A harm reporting system will create mountains of data, and as the system is developed, consideration must also be given to the structuring, storage, and analysis of this data, as well as what actions will be taken in cases of egregious or ongoing errors.

Thank you for the opportunity to provide my initial thoughts about the proposed project.

Regards,
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