Point of Care Errors

Keeping “Humans” and “Errors” Apart
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Provocate
Though Jennifer Raper had undergone several rounds of chemotherapy and a hysterectomy after discovering she had breast cancer in 2000, she was diagnosed with an unexpected pregnancy in June 2003. After going to several doctors, who couldn’t find a reason for her symptoms, she finally was admitted to a hospital where she gave birth to a healthy baby boy.

“If I could save one person from having to go through what I went through,” says Raper, “then it would be worth it to me.”

And she has, according to at least five of the women who saw her story.

Saving Other Women

“Jennifer’s story saved my life,” says Michele Kachurk, whose initial cancer diagnosis was based on months of elevated HCG levels, a hormone that is secreted when a woman is pregnant, but also when there may be signs of a rare form of cancer.

“I got my fight back,” says Kachurk, who was in her seventh month of chemotherapy when she saw Raper’s story. “I learned I was pregnant immediately after seeing Jennifer. I swore I knew. I just knew I was fine.”

So Kachurk sought another opinion at Memorial Sloan-Kettering hospital in New York. Doctors there now believe she never had cancer.

The ABCNEWS.com report of Raper’s story helped Shari Bradford-Royce avoid undergoing potentially catastrophic medical procedures.

“That could have been me,” says Bradford-Royce, a stay-at-home mom in Michigan who was about to undergo weekly chemotherapy. “Who knows what my doctors would have said would be the next step?”

She says that thanks to Raper, “I have my life back.”

High HCG Level
Objectives

• Be able to define the common terms in field of Risk Management

• Be able to review and understand a basic statistical analysis of Risk

• Be able to list the most common errors which affect a patient result for laboratory tests

• Be able to categorize the unacceptable and acceptable risks in your institution
HAVE FUN!
2016: Your new favorite word
44,000 to 98,000 deaths
PREVENTABLE medical mistakes
This report says medical errors such as indecipherable prescriptions cause the deaths of 98 patients a year, or is that 98,000? It's hard to read this. In any case, we're supposed to report them, or is that repeat them?

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“All men make mistakes, but a good man yields when he knows his course is wrong, and repairs the evil. The only crime is pride.”

— Sophocles, Antigone
You are here
“It is not the strongest of species that survive, nor the most intelligent, but the one most responsive to change.”

Charles Darwin
Causes

- 15-20% is mechanical failure
- >80% is human error
  - Active errors
  - Latent errors
• 210,000 – 400,000 deaths
Hospital Errors are the Third Leading Cause of Death in U.S., and New Hospital Safety Scores Show Improvements Are Too Slow

Washington, D.C., October 23, 2013 – New research estimates up to 440,000 Americans are dying annually from preventable hospital errors. This puts medical errors as the third leading cause of death in the United States, underscoring the need for patients to protect themselves and their families from harm, and for hospitals to make patient safety a priority.

Released today, the Fall 2013 update to The Leapfrog Group (Leapfrog) Hospital Safety Score assigns A, B, C, D and F grades to more than 2,500 U.S. general hospitals. It shows many hospitals are making headway in addressing errors, accidents, injuries and infections that kill or hurt patients, but overall progress is slow. The Hospital Safety Score is calculated under the guidance of the Leapfrog Blue Ribbon Expert Panel, with a fully transparent methodology analyzed in the peer-reviewed Journal of Patient Safety.

Leapfrog, an independent, national nonprofit organization that administers the Score, is an advocate for patient safety nationwide.

“We are burying a population the size of Miami every year from medical errors that can be prevented. A number of hospitals have improved by one or even two grades, indicating hospitals are taking steps toward safer practices, but these efforts aren’t enough,” says Leah Binder, president and CEO of Leapfrog. “During this time of rapid health care transformation, it’s vital that we work together to arm patients with the information they need and tell doctors and hospitals that the time for change is now.”
Risk Creep

Injuries and fatalities

- Nuclear Power?
- Airline accidents?
- Cars?

Skewed perception

Risks accepted – familiarity or saturation
Use Errors vs. User Errors

- *Use error* is repetitive and can be predicted.

- *User error* is due to fundamental errors by humans that has no possibility of prediction.

(Renamed Abnormal Use in the standards)
The Five Rights

- Right Patient
- Right Drug
- Right Dose
- Right Route
- Right Time
Medication Mistakes

Every year 2.5 billion prescriptions are filled by pharmacies and 3.75 billion drugs are administered at hospitals. Every year approximately 1.6 million people suffer injuries because of prescription errors.

Examples of Medication Mistakes
- Hospital Fails to Properly Input Prescription into Computer Database
- Wrong Medicine or Prescription is Administered
- Wrong Dosage is Administered
- Allergic Reactions to Medicine or Prescription
- Negligent prescription
- Failure to Recognize Drug Interactions
- Failure to Properly Instruct Patient on Drug Dosage and Administration
- Mistakes in Writing or Filling Prescriptions
- Failure to Know Proper Uses of Drugs

Avoid Getting the Wrong Prescription
- Confirm the Name of your Medication
- Ask Questions about How to Use the Medication
- Understand What your Medication Treats
- Read Labels and Follow Instructions
- Tell your Health Care Providers What Medicines you Take
- Keep a List of your Medications
- Follow your Medicine Schedule
- Keep Medicine in its Original Container
- Inspect your Medicine to Determine Whether it Looks or Smells Different

You may be Entitled to Compensation for:
- Medical Expenses
- Lost Income
- Pain and Suffering
- Wrongful Death (If Applicable)
- Other Losses

Call d'Oliveira & Associates at 1-800-992-6878 for a Free (No Obligation) Case Evaluation
• Remedial
  – Alleviate the symptoms of the existing problem

• Corrective
  – Eliminate the cause of existing problems or undesirable situation to prevent recurrence

• Preventive
  – Eliminate the cause of potential problems
Improving performance without changing the process is not process improvement, it’s performance improvement.

Tony Joseph
ICS4 Failures Lead to Patient Deaths

Fatal Error

The problem at the laboratory began when it ordered the reagent used in a Prothrombin Time Test. During the test, part of a patient's blood sample is mixed with the reagent, a protein called tissue thromboplastin, which causes clotting. The laboratory then measures how long it takes the blood to clot.

Each reagent includes a package insert that identifies its ISI (international sensitivity index) and different reagents have different clotting times. The ISI is used in the INR (international normalized ratio formula) that standardizes test results. The laboratory employee who tried to order a new, more sensitive reagent did not know the new reagent catalog number. The employee used the old reagent catalog number and added a special note asking for the more sensitive version. Somewhere along the line before the order reached the distributor, the special note was deleted and the old reagent was sent to the laboratory.

Upon arrival, the laboratory employees did not check the package insert that would have told them they had the old reagent with a different ISI. Using an incorrect ISI in the INR formula led doctors to believe their patients' blood was clotting more than it was, thereby causing doctors to prescribe larger doses of the drug warfarin, which is used to prevent blood clots and stroke. When using this drug the patient must be monitored very carefully. The discrepancy be-

continued on page 7
• e.r.
• Romano and Cordei

NOT THIS ONE, IDIOT!
If you aim at nothing, you’ll hit it every time.

Zig Ziglar
• Goal in Point of Care?
• Goal in the Laboratory?
• Goal in the Hospital?

Golden Rule: Do unto others as you would have them do unto your mother.
Is 99.9% Good Enough?

- 1 hour of unsafe drinking water every month;
- There will be no telephone, electricity or television for 15 minutes each day.

- 315 entries in Webster's Dictionary will be misspelled
- 880,000 credit cards in circulation will turn out to have incorrect cardholder information on their magnetic strips

- 22,000 checks will be deducted from the wrong bank accounts in the next 60 minutes.

- Your heart fails to beat 32,000 times each year.
- Twelve babies will be given to the wrong parents each day.
- 107 incorrect medical procedures will be performed by the end of the day today.
- 200,000 drug prescriptions will be filled incorrectly in the next 12 months.

- A typical day would be 24 hours long (give or take 86.4 seconds)

Jeff Dewar
One 19-year veteran says she quit her full-time job at Harrisburg Hospital because, as a nurse, “What they are expecting of you is physically impossible to do safely.”

Her advice to the public: “Don’t get sick. I’m serious.”
Perfect test result
On the right patient
Performed by a qualified operator simply and
Delivered quickly to a caregiver who can improve patient condition
ULTRA-COMPLEX

Health System
EDN, University, Multi-Hospital, VA

SIMPLISTIC

Physician Office Lab
While point-of-care testing (POCT) has significantly improved the timely delivery of diagnostic information for clinical decision making, the wide range of settings and operators involved in POCT add a layer of complexity to an institution’s effort to ensure consistently high-quality results.”

Gerald J. Kost, MD, PhD
What does the future of Point of Care testing look like?
"Nurse, get on the internet, go to SURGERY.COM, scroll down and click on the 'Are you totally lost?' icon."
What is your best strategy for reducing human error?
Is it great training and retraining/followup?
# Strategies for Error Reduction

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Power (leverage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fail-safes and constraints</td>
<td>High</td>
</tr>
<tr>
<td>Forcing functions</td>
<td></td>
</tr>
<tr>
<td>Automation and computerization</td>
<td></td>
</tr>
<tr>
<td>Standardization</td>
<td></td>
</tr>
<tr>
<td>Redundancies</td>
<td></td>
</tr>
<tr>
<td>Reminders and checklists</td>
<td></td>
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<tr>
<td>Rules and policies</td>
<td></td>
</tr>
<tr>
<td>Education and information</td>
<td>Low</td>
</tr>
</tbody>
</table>

No author listed. "Leveraging error reduction strategies". Institute for Safe Medication Practices. Pharmacy Today APhA. August 2013
The Perfect User

Navigation skills of a bat

Stamina of a camel

Memory of an elephant

Dexterity of a monkey

Visual acuity of an eagle

Image copyright William Hudson and Alex Brychta.

This creature is known as an elecamonglebat, being an unusual hybrid of elephant, camel, monkey, eagle and bat. It represents the perfect user during design meetings. Unfortunately, it is exceedingly rare in the wild.
• Easy to Implement
• Easy to Interface (Display, Print or Interface to any system)
• Easy to Use
• Easy to Manage
• Easy to Support

• Robust and Durable
• Technologically advanced
• Scalable from POL to Enterprise
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>CRITICAL Value</th>
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<tbody>
<tr>
<td>pCO₂</td>
<td>73 mmHg</td>
<td>70 mmHg</td>
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<tr>
<td>pH</td>
<td>7.10</td>
<td>7.20</td>
</tr>
<tr>
<td>pO₂</td>
<td>81 mmHg</td>
<td></td>
</tr>
<tr>
<td>HCO₃</td>
<td>24 mmol/L</td>
<td></td>
</tr>
<tr>
<td>BE</td>
<td>+2 mmol/L</td>
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</tr>
<tr>
<td>sO₂</td>
<td>85 %</td>
<td></td>
</tr>
<tr>
<td>TCO₂</td>
<td>73</td>
<td></td>
</tr>
<tr>
<td>Na</td>
<td>118 mmHg</td>
<td>119 mmHg</td>
</tr>
<tr>
<td>K</td>
<td>3.8 mmHg</td>
<td></td>
</tr>
<tr>
<td>iCa</td>
<td>1.62 mmHg</td>
<td></td>
</tr>
<tr>
<td>Glu</td>
<td>423 mmol/L</td>
<td>400 mmol/L</td>
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<tr>
<td>Hct</td>
<td>42 mmol/L</td>
<td></td>
</tr>
<tr>
<td>Hb</td>
<td>14 %</td>
<td></td>
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</table>
• Pre-Analytical
  – ID
  – Sample Collection
  – Sample Handling
  – Technique specific

• Analytical
  – Expired reagents
  – Degraded
  – Interfering Substances

• Post-Analytical
  – Printouts
  – Connectivity
  – Know which physician ordered
Heuristic

experience-based techniques that help in problem solving, learning and discovery. A heuristic method is used to rapidly come to a solution that is hoped to be close to the best possible answer, or 'optimal solution'.
Ten Usability Heuristics

- by Jakob Nielsen These are ten general principles for user interface design. They are called “heuristics” because they are more in the nature of rules of thumb than specific usability guidelines.

- **Visibility of system status**
  - The system should always keep users informed about what is going on, through appropriate feedback within reasonable time.

- **Match between system and the real world**
  - The system should speak the users’ language, with words, phrases and concepts familiar to the user, rather than system-oriented terms. Follow real-world conventions, making information appear in a natural and logical order.

- **User control and freedom**
  - Users often choose system functions by mistake and will need a clearly marked “emergency exit” to leave the unwanted state without having to go through an extended dialogue. Support undo and redo.

- **Consistency and standards**
  - Users should not have to wonder whether different words, situations, or actions mean the same thing. Follow platform conventions.

- **Error prevention**
  - Even better than good error messages is a careful design which prevents a problem from occurring in the first place. Either eliminate error-prone conditions or check for them and present users with a confirmation option before they commit to the action.

- **Recognition rather than recall**
  - Minimize the user's memory load by making objects, actions, and options visible. The user should not have to remember information from one part of the dialogue to another. Instructions for use of the system should be visible or easily retrievable whenever appropriate.

- **Flexibility and efficiency of use**
  - Accelerators -- unseen by the novice user -- may often speed up the interaction for the expert user such that the system can cater to both inexperienced and experienced users. Allow users to tailor frequent actions.

- **Aesthetic and minimalist design**
  - Dialogues should not contain information which is irrelevant or rarely needed. Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility.

- **Help users recognize, diagnose, and recover from errors**
  - Error messages should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution.

- **Help and documentation**
  - Even though it is better if the system can be used without documentation, it may be necessary to provide help and documentation. Any such information should be easy to search, focused on the user's task, list concrete steps to be carried out, and not be too large.
Tighter Control
= 
Higher Quality
= 
Improved Safety
= 
Better Patient Care !!
You can observe a lot by watching

Yogi Bera
Fishbone

Cause

- Equipment
- Process
- People

Secondary cause
Primary cause

Effect

- Materials
- Environment
- Management

Problem
Figure 4. Fishbone Diagram for Identification of Potential Failure Modes
### Risk Acceptability Matrix

<table>
<thead>
<tr>
<th>Probability of Harm</th>
<th>Negligible</th>
<th>Minor</th>
<th>Serious</th>
<th>Critical</th>
<th>Catastrophic</th>
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<tr>
<td>Frequent</td>
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<td>Improbable</td>
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<td>Acceptable</td>
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2.6 Risk Response Register

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<tr>
<th>Function</th>
<th>Risk</th>
<th>Person Accountable &amp; When</th>
<th>Due</th>
<th>P</th>
<th>I</th>
<th>RPRI</th>
<th>Residual P</th>
<th>Residual I</th>
<th>Residual RPRI</th>
<th>Mitigation Plan</th>
<th>Contingency Plan</th>
<th>Risk Status</th>
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<td>5</td>
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<td>5</td>
<td>15</td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
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Point of Care testing – the regulations
CLIA ‘88

• Accrediting Agencies
  – College of American Pathologists
  – The Joint Commission
  – COLA
  – State Medical Agencies (CLIA)
Clinical Laboratory Improvement Amendments (CLIA)

Equivalent Quality Control Procedures

Brochure #4

What are they, and when can I use them?

Information to assist your laboratories in meeting the CLIA quality control requirement options for unsurpassed (moderate and high complexity) test systems.

“We blew it”

Judy Yost, MA, MT

CMS Division of Laboratory Services (CLIA)
Laboratory Quality Control Based on Risk Management, Approved Guideline
IQCP
(Individualized Quality Control Plan)
You can’t manage what you can’t measure.

Bill Hewlett
Critical Success Factors

- Clear understanding of regulations / risks
- Standardize the process - Checklists
- Lockouts and forcing functions
- Open communication
- Positive feedback for successes
- Immediate corrective action
- Access to information
- PMA
“Don’t be encumbered by history. Go out and create something wonderful.”

Robert Noyce, Intel