

Domain 4: Manage Safety Risks

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Excerpts from: A primer on leading the improvement of systems

Donald M Berwick, *BMJ* 1996;312:619-622

The nurse called me urgently into the room. The child, she said, was in acute respiratory distress.

I had never met either Jimmy (the 6 year old boy) or his mother (an inner city single teenage parent) before. His asthma attack was severe, his peak expiratory flow rate only 35% of normal. Twenty years ago my next steps would have been to begin bronchodilator treatment, call an ambulance, and send the boy to hospital. That also would have been the story 10 years ago, or five, or two.

But today, when I entered the room, the mother handed me her up to date list of treatments, including nebuliser treatment with β_2 agonists that she had administered with equipment that had been installed in her home. It continued with her graph of Jimmy's slowly improving peak flow levels, which she had measured and charted at home, having been trained by the asthma outreach nurse. She then gave me the nurse's cellular telephone number, along with a specific recommendation on the next medication to try for her son, one that had worked in the past but was not yet available for her to use at home.

My reply was interrupted by a knock on my door. It was the chief of the allergy department in my health maintenance organization. He worked one floor above me in the health centre and, having been phoned by the outreach nurse, had decided to "pop down" to see if he could help. He also handed me a phial of the same new medication that the mother had just mentioned, suggesting that we try it.

Two hours later Jimmy was not in a hospital bed; he was at home breathing comfortably. Just to be safe the allergy nurse would be paying him a visit later that afternoon.

Improvement and change: a systems view¹ Not all change is improvement, but all improvement is change.

THE CENTRAL LAW OF IMPROVEMENT

“Every system is perfectly designed to achieve the results it achieves.” This aphorism encodes an understanding of systems that lies at the root of current approaches to making systems function better. The central law reframes performance from a matter of effort to a matter of design.

The central law of improvement implies that better or worse "performance" cannot be obtained from a system of work merely on demand. (A system of work here means any set of activities with a common aim--a doctor's practice, a hospital, or a national health care system.) It implies that the results of health care, such as mortality rates or the speed,

with which we address a patient's anxiety, are themselves properties of our system of care, just as the length of my maximum long jump is inherent in the nature of my body (which is also a system). Mere effort can, of course, achieve some improvements. But such improvement is not fundamental; it does not often represent a new level of capability.

CHANGE OF A SYSTEM, NOT CHANGE IN A SYSTEM

This change in Jimmy's care is change of a system, not change within a system.² For Jimmy, change within the system would have meant my trying harder not to admit or waiting longer before doing so; using more of a familiar drug, not turning to a new one; getting the child more quickly to a nebuliser, not moving the nebuliser, the peak flow meter, and the skill to the home.

We must be clear about the distinction between stressing the current system (relying on more of the same) and introducing a truly new system. The former butts without much effect against the walls of historical performance; the latter leaps over them.

Discussion:

1. What are the elements of the system in this case?
2. Consider what would have happened if one element of the system was not working properly.

Required reading:

Excerpts from Human error: models and management
James Reason BMJ 2000; 320: 768

Summary points

Two approaches to the problem of human fallibility exist: the person and the system approaches.

The person approach focuses on the errors of individuals, blaming them for forgetfulness, inattention, or moral weakness

The system approach concentrates on the conditions under which individuals work and tries to build defenses to avert errors or mitigate their effects.

High reliability organizations—which have less than their fair share of accidents—recognize that human variability is a force to harness in averting errors, but they work hard to focus that variability and are constantly preoccupied with the possibility of failure

System approach

The basic premise in the system approach is that humans are fallible and errors are to be expected, even in the best organizations. Errors are seen as consequences rather than causes, having their origins not so much in the perversity of human nature as in

“upstream” systemic factors. These include recurrent error traps in the workplace and the organizational processes that give rise to them. Countermeasures are based on the assumption that though we cannot change the human condition, we can change the conditions under which humans work. A central idea is that of system defenses. All hazardous technologies possess barriers and safeguards. When an adverse event occurs, the important issue is not who blundered, but how and why the defenses failed.

Error Management

Error management has two components: limiting the incidence of dangerous errors and—since this will never be wholly effective— creating systems that are better able to tolerate the occurrence of errors and contain their damaging effects. Whereas followers of the person approach direct most of their management resources at trying to make individuals less fallible or wayward, adherents of the system approach strive for a comprehensive management program aimed at several different targets: the person, the team, the task, the workplace, and the institution as a whole. High reliability organizations - systems operating in hazardous conditions that have fewer than their fair share of adverse events - offer important models for what constitutes a resilient system. Such a system has intrinsic “safety health”; it is able to withstand its operational dangers and yet still achieve its objectives.



So far, three types of high reliability organizations have been investigated:

- US Navy nuclear aircraft carriers;
- Nuclear power plants; and
- Air traffic control centres.
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The challenges facing these organizations are twofold:

- Managing complex, demanding technologies so as to avoid major failures that could cripple or even destroy the organisation concerned.
- Maintaining the capacity for meeting periods of very high peak demand, whenever these occur.

The organisations studied had these defining characteristics:

- They were complex, internally dynamic, and, intermittently, intensely interactive
- They performed exacting tasks under considerable time pressure
- They had carried out these demanding activities with low incident rates and an almost complete absence of catastrophic failures over several years.

Although, on the face of it, these organisations are far removed from the medical domain, they share important characteristics with healthcare institutions. The lessons to be learnt from these organisations are clearly relevant for those who manage and operate healthcare institutions.

Characteristics of High Reliability Organizations

- Preoccupation with failure
- Reluctance to simplify interpretations
- Sensitivity to operations
- Commitment to resilience
- Deference to expertise

Recommended reading:

Weick K E, Sutcliffe K M. Managing the Unexpected, 2nd Edition Wiley Books. 2007.

Anticipate and Recognize Problems: Consider the following case.

Charles Vincent et al. *BMJ* 2000;320:777-781

Mrs. B was booked for shared care. Her last child weighed 4.4 kg at birth and slight shoulder dystocia was noted at delivery. Mrs. B was referred to the consultant by the community midwife at 38 weeks as the baby felt large for dates. The ultrasound scan estimated the weight of the baby as 4.5 kg. A graded response to the findings on palpation and ultrasound was made bearing in mind the woman's previous obstetric history. Firstly, the pregnancy should not progress more than six days beyond the due date before induction of labour, rather than the usual 12-14 days. Secondly, it was recorded that no attempt should be made at a difficult mid-cavity instrumental delivery. Thirdly, the possibility of shoulder dystocia was anticipated and recorded to forewarn the labour ward staff.

Chronology:

0555: Mrs. B was admitted with ruptured membranes. Labour started shortly afterwards

0650: Vaginal examination showed her cervix to be 3 cm dilated. The fetal heart was monitored by external Doppler probe. At this stage Mrs. B requested an epidural, but the anaesthetist was not immediately available as he was finishing handing over on the intensive care unit. Mrs. B's labour proceeded rapidly and therefore an epidural was not carried out

0715: A scalp electrode was placed on the baby's head as the midwives were unable to monitor the fetal heart easily in view of maternal size and maternal distress. The trace showed the fetal heart rate to be normal

0750: A further vaginal examination was carried out. Mrs. B's cervix was 6 cm dilated, the fetal heart rate was normal with good variability. Pethidine was administered

0805: The cervix was fully dilated and pushing started. Mrs B was unable to cooperate with staff as she was in pain and very distressed

0814: Scalp electrode was removed as the head was crowning. The final readings of the fetal heart before the scalp electrode was removed showed marked decelerations with a decreasing trend. The delivery did not proceed and the head remained stationary. The external Doppler probe was reattached and showed fetal heart rate at 160-170 beat/min

0833: Medical help was sought. The obstetric registrar and the duty consultant came immediately and quickly diagnosed shoulder dystocia. They carried out a McRoberts maneuver and then applied suprapubic pressure; the baby was delivered at 0839

0839: The infant was severely compromised with no heart beat. He was resuscitated and ventilated and then transferred to the special care baby unit but died the next day.

Safety Practices that reduce the risk of Adverse Events: Medication Management

Adverse drug events due to medications are considered one of the most common type of adverse events in paediatric practice. In a multicentre study using a trigger tool to detect adverse events, Takata reported a mean rate of 11.1 ADEs per 100 patients; 22% were considered preventable, and 97 % resulted in mild temporary harm. (Takata GS, Mason W, Taketomo C, Logsdon T, Sharek PJ. Development, testing, and findings of a paediatric-focused trigger tool to identify medication-related harm in US children's hospitals. *Paediatrics*. 2008;121(4):e927-35.) Children are particularly susceptible to medication errors given the mg/ kg dosing and development dependent physiology and drug metabolism.

Drug errors can be considered at the prescribing, dispensing and administration stages of the medication process.

Question:

What types of errors can happen at each of these phases? How could you mitigate against errors at each of these phases.

A number of interventions have been targeted specifically to improve patient safety related to medication management. They include:

1. Computerized physician/ provider order entry
2. Standardization of drug concentrations and limitation of concentrations available
3. Removal of concentrated electrolytes from wards
4. Double checking of high alert medications
5. Medication reconciliation

1. Computerized physician/ provider order entry refers to direct computer entry of medication orders by the prescriber. This reduces opportunity for transcription error and errors related to illegible handwriting. It can facilitate calculations if there is a built in calculator. Major strengths are derived from the decision support that can be embedded within the system.

2. Standardization of drug concentrations and limitation of concentrations available
The rule of six (a mathematical equation that calculates the amount of drug (milligram) that should be added to 100 mL of fluid, so that 1 mL/hr delivers the drug at a rate of 1 µg/kg/min) can no longer be used. The use of standardized concentrations of medications reduces variability in the delivery of the medications to reduce the potential

for error. The use of “smart pumps” that have built in software with prescribed dosing limits of the various medications is an additional safety net.

3. Removal of concentrated electrolytes from wards

Administration of concentrated KCl to a patient can be fatal. All efforts must be put in place to prevent this from occurring. Removing concentrated electrolytes from the ward is a forcing function: if it’s not there, it can’t be administered!

4. Double checking of high alert medications refers to a process whereby two individuals independently check all calculations and patient identifiers prior to administering the medication. Given the time and human resources required, this process is usually restricted to high alert medications (ie those with a narrow toxic-therapeutic margin eg: insulin, opioids, heparin). Independent double checks are also used for blood transfusions.

5. What Is Medication Reconciliation?

(Safer Healthcare Now! Getting Started Kit 2007)

[http://www.saferhealthcarenow.ca/EN/Interventions/medrec_acute/Documents/Med%20Rec%20\(Acute%20Care\)%20Getting%20Started%20Kit.pdf](http://www.saferhealthcarenow.ca/EN/Interventions/medrec_acute/Documents/Med%20Rec%20(Acute%20Care)%20Getting%20Started%20Kit.pdf)

The ultimate goal of medication reconciliation is to prevent adverse drug events (ADEs) at all interfaces of care, for all patients. The aim is to eliminate undocumented intentional discrepancies and unintentional discrepancies by reconciling all medications, at all interfaces of care. This is a system change that requires time and commitment.

Medication Reconciliation is a formal process of:

1. Obtaining a complete and accurate list of each patient’s current home medications—including name, dosage, frequency and route,
2. Using that list when writing admission, transfer and/or discharge medication orders, and
3. Comparing the list against the patient’s admission, transfer, and/or discharge orders, identifying and bringing any discrepancies to the attention of the prescriber and, if appropriate, making changes to the orders. Any resulting changes in orders are documented

Medication errors that can be prevented by reconciling medications may include but not be limited to, inadvertent omission of needed home medications, failure to restart home medications following transfer and discharge, duplicate therapy at discharge (the result of brand/generic combinations or formulary substitutions), and errors associated with orders having incorrect doses or dosage forms.”

Leonard et al reported a multimodal strategy to reduce the incidence of adverse drug events. (Leonard SM, Cimino M, et al. Risk reduction for adverse drug events through sequential implementation of patient safety initiatives in a children’s hospital. *Pediatrics* 2006: 118;1124-1129)