

Engineering Healthcare

a report by

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Thousands of medical errors, with potentially dire consequences, occur every year in healthcare organisations worldwide. Beyond the human toll, errors result in billions of dollars in lost individual income, lost corporate productivity and healthcare expenditures that could otherwise be put to constructive use.

The fact that errors occur is not surprising, given the complexities of healthcare. Human beings routinely make mistakes and new technology, the need for fast action and the expanding availability of new drugs and procedures all contribute to the occurrence of errors.

For many years these errors were rarely acknowledged, even within healthcare organisations. The fear of legal or professional retribution and guilt and shame have conspired to keep healthcare professionals from discussing, let alone analysing and understanding, the underlying causes of these errors.

A New Approach

To combat this pressing issue, healthcare is now turning to engineering concepts. Engineering, with its commitment to and proven techniques for proactive risk assessment, can help healthcare organisations identify processes that are prone to error and develop effective resolutions before adverse events occur.

Engineering, which has long been integral to the maintenance of safe physical environments in healthcare organisations, is moving to centre stage in helping to reduce errors and prevent adverse events. This transition represents a critical effort to get in front of the traditional reactive root cause analyses of adverse events. The latter are frequently subject to 'hindsight bias' and 'blinder effects'. An organisation may become so caught up in the emotion of the event that it becomes blind to other risky processes. The best root cause analyses examine all risk points in a process on a prospective, rather than retrospective, basis.

Based on this reality, all accredited hospitals in the

US are now required to proactively seek out high-risk processes, analyse them using failure mode, effects and criticality analyses and redesign them to improve the safety of their performance. The new safety standards cover all activities within an organisation that relate to the maintenance and enhancement of patient safety, such as performance improvement, monitoring of environmental safety and risk management. The standards do not require the creation of new structures or 'offices' within the organisation. Rather, they emphasise the need to integrate all patient safety activities, both existing and newly created, throughout the fabric of the organisation, and to achieve this objective under the specific aegis of the organisation's leadership.

While the standards focus on patient safety, it would be difficult and indeed inappropriate to create an organisation-wide safety initiative that does not involve staff and visitors. Furthermore, many of the activities taken to improve patient safety (e.g. security, equipment safety, infection control) directly impact on staff and visitors as well as patients.

Proactive identification and management of potential risks to patient safety not only avoids hindsight bias but also eliminates the reactive fear of disclosure, embarrassment, blame and punishment that can arise in the wake of an actual adverse event. In fact, effective reduction of medical/healthcare errors and other factors that contribute to unintended adverse patient outcomes in a healthcare organisation requires a culture in which organisation leaders and staff willingly and actively identify and manage errors and risks to patient safety. Such an environment encourages the acknowledgment of the reality of human error; the initiation of actions to reduce risk of error; a focus on process and system analyses; and minimisation of individual blame or retribution for involvement in a medical/healthcare error.

The principal objectives are to promote organisational learning about medical/healthcare errors and to support the sharing of that knowledge to effect behavioural changes that lead to improvements in patient safety. The leaders of the

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organisation are responsible for fostering such an environment through personal example and through establishment of mechanisms that support effective responses to actual occurrences and encourage the identification of vulnerable processes that would benefit from proactive analysis.

Failure-mode factors

High-risk processes tend to share the following characteristics:

- variable inputs – inputs always affect outcomes; patients (the principal input) are highly variable;

based, in part, on information published periodically by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) that identifies the most frequently occurring types of sentinel events and patient safety risk factors.

The following proactive risk reduction activities should be conducted:

- assessment of the intended and actual implementation of the process to identify the steps in the process where the vulnerability to failure is the greatest (i.e. potential failure modes);

Engineering... can help healthcare organisations identify processes that are prone to error and develop effective resolutions before adverse events occur.

- complexity – simple is safer than complex, yet healthcare processes are usually – and sometimes unnecessarily – complex;
- non-standardised – inconsistent process tends to produce inconsistent results;
- tightly coupled – steps that follow each other too closely may allow a variation to go unnoticed or, alternatively, to be magnified in a ‘cascade of failure’;
- heavily dependent on human interaction – humans are prone to making errors, particularly where the lack of system redundancies permits errors to occur;
- hierarchal versus team culture – communication breakdowns create significant exposure to potential error. Each healthcare professional, regardless of rank, must feel free to speak up;
- tight time constraints – the likelihood of failure increases with less time to think critically and respond; and
- loose time constraints – too much time to perform tasks may breed tardiness.
- for each identified failure mode, determination of the possible effects on patients, and how serious those effects could be;
- for the most critical failure modes, completion of a root cause analysis to determine why the variation (the failure mode) may occur;
- redesign of the process and/or related systems to minimise the risk of the failure modes or to protect patients from the effects of the failure modes;
- testing and implementation of the redesigned process;
- identification and application of measures of the effectiveness of the redesigned processes; and
- design of a strategy for maintaining the effectiveness of the redesigned process over time.

Setting Priorities

Hospitals are expected to establish a framework or criteria for determining performance improvement priorities. The hospital’s priority-setting process should take into account emerging issues such as those identified through data collection and assessment, unanticipated patient care occurrences, changes in regulatory requirements, changes in the environment of care or changes in the community.

The planning process should give priority consideration to the following:

Proactive Activities

New patient safety standards require hospitals to select annually at least one high-risk process for proactive risk assessment. This selection is to be

- processes that affect large numbers of patients;
- processes that place patients at risk if not performed well, if performed when not indicated, or if not performed when indicated; and
- processes that have been or are likely to be problem-prone.

National Patient Safety Goals

The JCAHO has also set priorities by establishing National Patient Safety Goals to help accredited organisations address specific areas of concern regarding patient safety. Each goal includes no more than two succinct, evidence-based or expert-based recommendations. To ensure a focus on priority safe practices, no more than six goals are established for any given year. In succeeding years, certain goals are likely to be continued, while others will be replaced due to emerging new priorities.

For each of the National Patient Safety Goals, there are clear, evidence-based recommendations to help healthcare organisations reduce specific types of healthcare errors.

The 2003 goals were developed by an expert advisory group comprising physicians, nurses, risk managers and other professionals. The advisory group identified a total of 44 expert-based and evidence-based recommendations that include the 11 associated with the 2003 goals. The remaining recommendations constitute an initial pool upon which future National Patient Safety Goals may be based.

There are more than 17,000 JCAHO-accredited healthcare organisations that provide care relevant to the goals and, beginning 1 January 2003, they will be evaluated for compliance with the recommendations or implementation of acceptable alternatives.

The National Patient Safety Goals identified for 2003 are as follows:

- Goal 1 – Patient Identification
- Goal 2 – Communication
- Goal 3 – High-alert Medications
- Goal 4 – Wrong-site Surgery
- Goal 5 – Infusion Pumps
- Goal 6 – Alarm Systems

Goal 1 – Improve Accuracy of Patient Identification

- Use at least two different patient identifiers (neither of which should be the patient's room number) whenever taking blood samples or

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Table 1: Sample Failure Mode, Effect and Criticality Analysis for Hypothetical Medication Use Process in Operating Rooms

Process	Pharmacy	Dispense	OR	Transfer	Sterile field	Administer	Patient
Potential failure modes	Alike-looking drugs Multiple concentrations	Wrong drug Wrong concentrations		Switched drugs Contamination		Wrong drug Wrong dose	
Potential effect on patient	8	8		10		10	
Frequency of failure mode	7	3		2		3	
Likelihood of reaching patient	3	4		6		10	
Criticality of failure mode	168	96		120		300	
Root causes	Open formulary Ambiguous labels	Alphabetical storage Ambiguous labels		Unnecessarily complex process; approved procedure not consistently followed		No means of verifying drug/dose after transfer to sterile field	
Strategies	P&T Committee review/redesign of formulary content & process	Redesign storage system; introduce bar coding		Simplify procedure; eliminate open-vessels for IV drugs; monitor compliance		No action required; risk eliminated earlier in process	

administering medications or blood products.

- Prior to the commencement of any surgical or invasive procedure, conduct a final verification process, such as a ‘time out’, to confirm the correct patient, procedure and site, using active – not passive – communication techniques.

Goal 2 – Improve Effectiveness of Communication Among Care-givers

- Implement a process for taking verbal or telephone orders that requires a verification ‘read-back’ of the complete order by the person receiving the order.
- Standardise abbreviations, acronyms and symbols used throughout the organisation, including a list of abbreviations, acronyms and symbols not to be used.

Goal 3 – Improve Safety of Using High-alert Medications

- Remove concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, sodium chloride >0.9%) from patient care units.
- Standardise and limit the number of drug concentrations available in the organisation.

Goal 4 – Eliminate Wrong-site, Wrong-patient, Wrong-procedure Surgery

- Create and use a pre-operative verification process, such as a check list, to confirm that appropriate documents (e.g. medical records, imaging studies) are available.

- Implement a process to mark the surgical site and involve the patient in the marking process.

Goal 5 – Improve Safety of Using Infusion Pumps

- Ensure free-flow protection on all general-use and patient-controlled analgesia intravenous infusion pumps used in the organisation.

Goal 6 – Improve the Effectiveness of Clinical Alarm Systems

- Implement regular preventive maintenance and testing of alarm systems.
- Ensure that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit.

Conclusion

No single approach, organisation or expert can provide an exact blueprint to ensure patient safety. It is clear, however, that healthcare organisations can no longer afford to wait for errors to occur before they initiate efforts to improve their patient care processes. Healthcare providers and practitioners must shift from merely hoping that everything will go right to actually building safety into the system.

Healthcare engineers need to become centrally involved in this effort by sharing and applying their expertise in systems analysis and design to the full scope of patient care activities. The effective application of the science of engineering can become a major asset in preventing human error from actually reaching the patient. ■