



HUMAN ERROR PREVENTION: SOLUTIONS AND ANSWERS

by Martin Lush

Did you know the third leading cause of death in U.S. hospitals is human error? Researchers estimate that 250,000 people die every year from medical errors in the U.S. alone. Worldwide, human error is the third leading cause of death behind heart disease and cancer.

Unfortunately, society usually responds to this type of news with a 'who can we blame?' headline. In other words, the focus is on the person, not the systems. People get retrained, often disciplined and sometimes fired. But the underlying systems usually remain unchanged, and mistakes continue to happen and risks continue to escalate.

Consider this real-life example about syringe drivers, which are frequently used in palliative care to deliver medicines over a fixed time period. The syringe is loaded and the injection rate set.

- > A patient received rapid dosing because the flow rate had been incorrectly set at 15 ml/hr instead of at 1.5 ml/hr. A small error with a big impact.
- > How did this happen? When setting the flow rate, the nurse added an extra decimal point entering 1..5, which is easily done. Recognizing her mistake, she hit 'backspace' to remove the renegade decimal point. Most people would likely have done the same.
- > Unfortunately, this action unintentionally removed both decimal points, leaving a flow rate of 15 ml/hr. In the context of the multiple distractions of a busy hospital ward, stress and fatigue, the nurse didn't notice the mistake.



The nurse was fired due to gross negligence, but the systems were not re-evaluated. No one considered redesigning the equipment or building in system safeguards to prevent a repeat incident.

ERROR REDUCTION – WHAT'S POSSIBLE

It is possible to reduce errors and save money. An NSF client who attended our error reduction course reduced repeat errors by 67 percent in six months and has so far saved \$1.2 million.

- > Human error is the consequence, but rarely the cause, of mistakes. Human error must be the investigation starting point, not automatically its conclusion.
- > There is no such thing as single root cause for any error or mistake.
- > If you want to prevent errors happening, focus on the system not the person.
- > Focus on latent, not active, failures (preventive versus corrective controls).



REGULATORY PRESSURE TO REDUCE HUMAN ERROR

Pharma regulators are getting increasingly frustrated by repeat errors and the focus on the person, not the system. This is made crystal clear in the GMP guidelines enforced by EU regulators. Take a look at the EU GMP's Volume 4, 1.4, xiv (redacted):

*"An appropriate level of root cause analysis should be applied during the investigation of deviations... in cases where the true root cause(s)... cannot be determined; consideration should be given to identifying the most likely root cause(s)... **Where human error is suspected or identified as the cause, this should be justified having taken care to ensure that process, procedural or system based errors or problems have not been overlooked.**"*

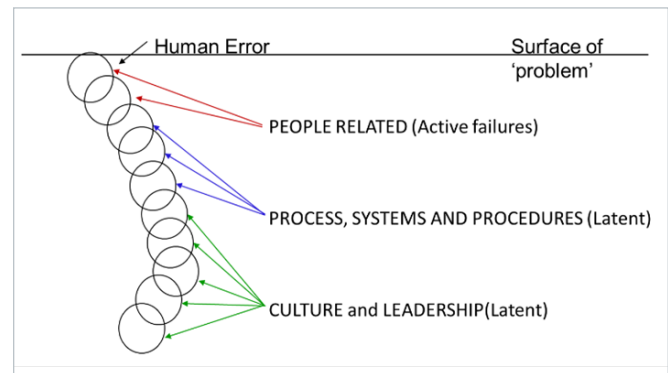
The regulation requires that if you conclude people are to blame for mistakes, you have the data to rule out over complexity, poor process design, inappropriate KPIs and other causes.

REDUCING YOUR ERROR BILL AND YOUR RISKS

Error reduction isn't a single project, but a matter of corporate culture. It requires a lot of effort, but is ultimately less work than continually fixing errors. Can your company really afford your 'error bill'? One pharma company estimated the cost of human error to be approximately \$2.2 million per year and another in excess of \$150 million.

At NSF we're fortunate to work with the very best companies and organizations that have successfully reduced their error bill and legacy risk. We've studied their methods and identified their top error prevention practices, which include the 'error chain' and 'latent failures'.

THE ERROR CHAIN



If you want to prevent repeat incidents, focus on identifying the error chain, rather than looking for one or two 'root causes'. Remember:

- > Every error results from multiple causes or contributing factors.
- > Errors happen when these come together to form an error chain.
- > The focus of any problem solver (deviation investigator) must be to find and fix as many contributing factors as possible, which includes fixing the underlying (latent) failures.

LATENT AND ACTIVE FAILURES

Active failures are the mistakes made by people in the workplace like a nurse on a busy, chaotic ward.

Latent failures, on the other hand, lurk beneath the surface, representing system weaknesses and problems. For example:

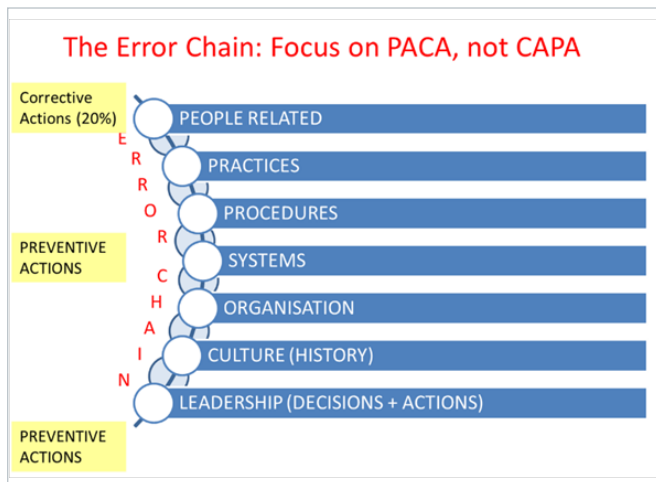
- > Poor workplace design causing distraction
- > Overly complex procedures that just confuse
- > Lack of adequate education
- > Absent supervision to support, guide and mentor the less experienced
- > A rampant blame culture triggered by poor KPIs



WHAT YOU CAN DO

If you want to reduce your error bill and legacy risk:

- > **Focus on looking for the error chain.** The term root cause(s) programs busy people to stop at the surface of the problem and focus on the person, not the system. The incident report gets closed quickly, but the error returns and risk increases.
- > **Hunt down the latent system-related errors** and weaknesses and fix as many of these as possible.
- > **Use FMEA** and similar techniques as they were intended to prevent risk, not to respond to it. During the design phase, ask 'what can go wrong' and engineer it out.
- > **Move from CAPA to PACA.** Make 'PA' your priority. Eighty percent of your actions should be preventive and 20 percent corrective. The other way around is firefighting.



MORE INFORMATION

Most of us at NSF are industry veterans of 30 years plus. We know the pressures of reducing costs, lead times and regulatory risk. We've been in your shoes and we want to help.

- > Access our human error publications that will help you reduce your error bill and legacy risk: www.nsf.org/newsroom/publications/category/human-error-prevention
- > Register for one of NSF human error courses (www.nsf.org/training-education/training-pharma-biotech/human-error-prevention).
- > If you prefer a customized error prevention course to reduce your error bill, contact martinlush@nsf.org.
- > Participate in our **human error prevention interest group** on LinkedIn to share experiences, ideas and solutions.

ABOUT THE AUTHOR

Martin Lush has over 30 years' experience in the pharmaceutical and healthcare industry. He has held senior management positions in QA, manufacturing, QC and supply chain auditing and has conducted audits and education programs for many hundreds of companies in over 25 countries.

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