Mistake Proofing and Zero Defects

Module 8
Mistake Proofing: Key Points

- Mistake proofing prevents mistakes before they create defects.
- Mistake proofing eliminates rework, reduces costs, and improves lead time performance.
- It is important to eliminate the root cause, not just the symptom, so the problem doesn’t show up again.
- The three main methods for mistake proofing are mechanisms/devices, inspection and visual control.
Errors and Defects

An error or mistake is defined as something done incorrectly through a misunderstanding, or as the result of an unreliable or unstable process.

A Defect is an Uncorrected Error.
Mistake Proofing

Purpose:
- Mistake proofing prevents mistakes before they create defects.

Why Do Mistake Proofing?
- Eliminate Rework.
- Improve Quality.
- Reduce Cost.
- Improve Lead Time (especially in relation to the predictability of cycle times).
- Patient Satisfaction.
- Zero Quality Control (end of line inspection).
- Improve Patient Safety.
- Improve Staff Engagement and Morale.
Recognizing Mistake-Prone Situations

A mistake-prone situation exists when it is possible to create an error while doing a task, procedure, or providing a service because the process being used is unreliable or unstable.

Some common mistake-prone situations.

- Critical clinical protocol or procedure requirements.
- Inadequately maintained instruments and equipment.
- Ineffective standard procedures and processes.
- Infrequent occurrence of a task or process.
- Multiple parts, processes, or steps.
- Poor environmental conditions.

- Revisions or changes.
- Short-cuts and workarounds.
- New products, processes or people.
- Multiple handovers.
- Multiple suppliers.
- Same information in numerous places.
- Repetitive, fast-paced operations.
Root Cause

It is important to find and eliminate the root cause, not the symptoms, so the problem will not occur again.

Once the root cause is found, then the corrective action must be taken to prevent the error from occurring again. Otherwise, we create a defect loop where the error occurs time and again, generating defect after defect.

Ask “why” 5 times to get to the root cause!
The Defect Loop

AN ERROR TAKES PLACE! (CAUSE)

A defect occurs as a result

The defect is identified and documented

The defect is corrected

Corrective action is implemented!

DOES THE CORRECTIVE ACTION ALTER THE PROCESS OR THE DESIGN TO PREVENT RECURRENCE OF THE DEFECT?

DEFECT IS ELIMINATED!

YES

NO
Mistake Proofing Systems

- Mistake-proofing systems, also called poka-yoke systems, help prevent mistakes before they become defects.

- A poka-yoke is a mechanism, device, or process that eliminates defects by preventing, correcting, or drawing attention to human errors as they occur.

- Poka-yoke systems use electronic or passive devices to make sure inspection happens reliably. Visual control and inspection can be used when implementing a mistake proofing system in a process where a device cannot be applied. The best ideas for how to apply them often come from the people doing the work.

- Poka-yoke systems prevent defects using two approaches.
  1. A control system stops the equipment or process when an irregularity occurs.
  2. A warning system signals the staff person to stop the machine and/or process to address the problem.
Mistake Proofing
Mechanisms/Devices

There are three main methods for applying Mistake Proofing mechanisms or devices:

1. **Contact methods** work by detecting whether a product makes or loses physical contact with a sensing device.  
   *Example: Bed alarms.*

2. **Fixed-value methods** can be used when a fixed number of parts must be attached to the product, or when a fixed number of operations needs to be done at a process station.  
   *Example: OR sponge count/needle count.*

3. **Motion method** is used to sense whether a motion or step in the process has been carried out within a certain time, such as a machine’s cycle time  
   *Example: Pain medication pumps.*
Points for Mistake-proofing systems

- Mistake-proofing systems do not need to be fancy or expensive.
- Many mistake-proofing systems are quite simple and inexpensive.
- The people who know the equipment and processes are best qualified to suggest solutions.
Poka-yoke Devices in Healthcare


[www.ahrq.gov](http://www.ahrq.gov)
An anti-scald plug

The holes for the pins are located at 12 o’clock and 5 o’clock. Also, the oxygen outlet is green, and the medical air outlet is yellow.

A wristband with multiple, peel-off, adhesive labels

When inflated fully, this bulb indicates that the intubation tube has been successfully inserted into the trachea.
If the plunger in this syringe pulls out easily, the tube has been properly inserted.

This watch vibrates to remind users to take medication.

Package conveys detailed dosing instructions.

Magnetic fire doors.
A bed monitor with sensor built into the bed

A patient's medical records can be stored in this wristband

The pharmacy inventory-picking robot increases accuracy
This scale with a child’s seat prevents injuries during weighing.

Inside the red line is a quiet, no-interruption zone.

This syringe prevents the accidental intravenous administration of oral medication.

Sponges containing radio-opaque substances are more easily found after surgery.
The urine bag and catheter have valves designed to allow fluids to flow only one way.

An electronic sensor provides robust security to prevent infant abductions.

The sticker provides a visual signal that the cabinet has been fully stocked.

A misplaced blood pressure cuff gives an inaccurate reading and triggers alarms.
Drug interaction software notifies the pharmacist of an incorrect prescription

A sponge-counter bag

A commercially-available automatic wheelchair-locking device

St. Joseph’s Hospital says “It’s OK to ask, ‘Did you wash your hands?’”
Mistake-Proofing

How to Get to Zero Defects

This original profound presentation was created by Dr. Robert Caplan, M.D., Virginia Mason Medical Center, Seattle, WA. as part of his certification requirement as a Lean Kaizen Leader under the supervision of John Black, JBA LLC. The content is based on the book by Shigeo Shingo, Zero Defects, Productivity Press.
Expectations about Outcome in Healthcare

Perfection is impossible

Injuries are inevitable

Perfection is possible

Injuries are avoidable

1 2 3 4 5
Perfection is so hard…

How about something close?
Happy about 99.9%?

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<th>Event</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Major Airplane Crash / Week</td>
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<tr>
<td>Wrong Surgery / Week</td>
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<td>Lost Mail Pieces / Hour</td>
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<tr>
<td>Wrong Account Deduction / Day</td>
<td>22,000</td>
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<tr>
<td>Lost IRS Documents / Year</td>
<td>2,000,000</td>
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The customer with a defective product is 100% dissatisfied

(The other 999 good products are invisible.)
Why Do We Keep Hurting Patients with Healthcare?

- We don’t believe perfection is possible.
- We believe that mistakes are unavoidable.
- We believe progress outweighs risk.
- We lack management tools for making defect-free healthcare.

46,000-98,000 preventable deaths / year
Another view…

Zero-defects is possible
Parachute Packers

- Most of us are taught that nothing is perfect.

- In WWII, aircraft crewmen were informed that their parachute failure rate was 3%.

- The “Zero Defects” goal was reached when the parachute packers were told that they would test the parachutes they packed by jumping from the planes themselves.
Shigeo Shingo

- Industrial management innovator.
- Chief consultant to Toyota.
- Developed “zero quality control” – eliminating the need for inspection of results.
”… I cannot marvel at how thoroughly I had been under the spell of statistics. I can only feel that I had been so taken by the magic of statistical methods that I had forgotten to pursue the nature of quality control itself. Only when I happened on the poka-yoke idea and the notion of trouble-free 100 percent inspections did I realize that one did not have to use statistics …

…the implementation of 100 percent inspections and rapid feedback and action cut defects dramatically. At that point, I looked into the nature of quality control and arrived at the idea of a Zero QC system.

…The essential goal of Statistical Quality Control methods is to reduce defects, a passive goal that accepts some level of defects is inevitable. In contrast a Zero QC system pursues the active objective of eliminating defects …”
What is Inspection?

- One of the basic features of flow.
- A way to protect the patient from receiving a defective product.
- Waste - if used incorrectly.
What Do We Want the Inspector to Find?

**Reversible**
Caught before going downstream.

**Irreversible**
Moves far downstream or to the end.

**Mistake**
Root cause is obvious.
Remedy is easy, immediate.

**Defect**
Root cause is obscure.
Remedy is hard, delayed.
Why *Distinguish* Between **Mistakes** and **Defects**?

- **Mistakes** are inevitable…but reversible.
- **Defects** are mistakes that were not fixed soon enough…and are now relatively permanent.
- If you fix mistakes soon enough, your work will have zero defects.
- Mistakes are least harmful and easiest to fix the closer you get to the time and place they arise (the reverse is also true).
“Yes, but take away the rodent droppings and the occasional shard of glass, and you’ve still got a damn fine product.”
Choices for Place of Inspection

Within Step

Just After

Just Before

Outside

Process step

Good Product

Mistake

Defective Product
Shingo’s First Breakthrough: Inspect-and-Fix at the Source

- Workers forgot to put a spring into either the ON or OFF button on the console.
- Two springs presented in a dish, along with console.
- If the dish was empty at the end of the process, the springs were in place.
Two Types of Source Inspection

- **Self-check**
  
  Check within or just after process step. Flaws are fixed before going forward.

- **Successive check.**
  
  Next process checks prior process work. Flaws are sent back to be fixed.
Self-Check vs. Successive Check

<table>
<thead>
<tr>
<th>Within Step</th>
<th>Just After</th>
<th>Just Before</th>
<th>Outside</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
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</table>

- **Process step**
- **Good Product**
- **Mistake**
- **Defective Product**
Shingo’s Second Breakthrough: There is an “Ideal” source check

Mistake Proofing : Poka-yoke

Automatically detects, stops, and fixes within the process step itself.
**Poká-yoke** is the most powerful form of Self-Check

- Usually *built into* machine function.
- Provides objective and immediate feedback and corrective action if a mistake occurs.
- Lowest-cost way to do 100% inspection.
Where is **Poká-yoke**, **Self-Check**, **Successive Check**?

**Process**  | **Good Product** | **Mistake** | **Defective Product**
---|---|---|---
1 | | |
2 | | |
3 | | |
Source Check: Key Points

- *Poka-yoke* guards against the human tendency to forget or become inattentive and is the **fastest**.

- *Self-check* gets the fastest corrective action when poka-yoke isn’t possible…but suffers from **subjectivity and compliance**.

- *Successive check* is the **last chance** for JIT correction, useful when the upstream process has no checks or unreliable checks, but suffers from **time delay and compliance**.
Inspection Levels and Stopping the Line
Level 1: Customer Inspects and Finds Defect (OIG, DOH, Malpractice Suit)

Feedback

Suppliers 1 2 3 4 5 Customers

Mistake Occurs

Customer finds defect
Level 2: Company Inspects at End of Process (QA, Audit, Narcotic Count)

Feedback

Suppliers 1 2 3 4 5 Customers

Mistake Occurs Inspector finds defect
Level 3: Work Unit Inspects and Corrects (Needle and Sponge Count)

Feedback

Suppliers → 1 → 2 → 3 → 4 → 5 → Customers

Mistake Occurs

Worker finds defect

Worker finds defect
Level 4: Self-Inspection and Correction (Patient ID, Surgery Site Check)

Mistake detected and corrected
Level 5: *Process Redesign* to Eliminate Mistakes (Pin index, CPOE)
Where is Source Check the Most powerful?

Level 5: Poka-yoke
Level 4: Self check
Level 3: Successive check
OR gas hoses are color coded and have unique connectors

Level 5 Inspection
Anesthesiology: Lines are color-coded and have unique fittings to avoid hooking the wrong hose to the wrong source.
Cath Lab: Imaging equipment has built-in stop to avoid crushing the patient.
Cath Lab: Imaging equipment has built-in stop to avoid crushing the patient.
The Lean Strategy for Zero-Defects

- *Inspect* for mistakes *at the source*.
- *Every employee* is an inspector.
- *Fix* every mistake *at the source*.

When you can’t fix on-the-spot: **STOP**.
Source Check is **JIT Inspection**

- Just the amount needed.
- Just at the place needed.
- Just at the time needed.
End-Inspection is Ridiculously Wasteful

- Lack of feedback hides the root cause.
- Sampling (SQC) is a no-win strategy:
  No guarantee of zero-defect.
  The fix is wasteful if a defect is found.
- More inspectors and inspection increase defect detection, but not remedies.
- *In healthcare, end-inspection is too late.*
Mistake Proofing and Visual Control

- Visual Controls help people respond quickly and effectively to problems by making abnormalities and waste obvious to everyone.
- Visual Controls are often instrumental in mistake proofing, especially in manual processes, where mechanisms/devices are not an option.
- Signs and Andons (alarm lamps) can alert staff to problems.
- Help everyone focus on finding the root causes of problems and making improvements.
- Visual Controls only make abnormalities visible. It’s up to people to take corrective action.
Examples of Mistake Proofing with Visual Control

Clinic room flags alert providers of next process or patient needs

Used with permission / Seattle Children’s Bellevue Clinic and Surgery Center
Examples of Mistake Proofing with Visual Control

Visual reminder to perform a final Self Check for specimen labeling prior to sending to the lab

*Used with permission of Saskatchewan Ministry of Health*
Zero-Defects = Healthcare Safety

- Healthcare is a product with safety in every step.
- Every safety mistake should be corrected as soon as possible as close as possible to its point of origin.
- Anyone can stop the line for safety (PSA).
- The goal is zero safety defects in healthcare.
Mistake-Proofing Summary

- Defects are caused by inappropriate procedures or standards, excessive variability, damaged or excessively variable material, worn machine parts, or human mistakes.

- The three main methods for mistake-proofing are mechanisms/devices, inspection and visual control.

- Mistake-proofing systems need not be fancy or expensive. Many are quite simple and inexpensive.

- The people who know the equipment, machines and processes best suggested many of the solutions.