TG100 Implementation Guide – Quality Management

Quality Management

The final video in this series is intended to give some guidance on a quality management program, one that includes risk-based quality management and also references for other types of quality work.

By now, we have reviewed some risk assessment tools. After learning from a process map, analyzing and ranking potential failures and their pathways, the most impactful work comes next.

"How am I going to build a safer system?" "How am I going to manage weaknesses that were identified?" "What tools do I use to prevent failures?" There are a few guidelines available for quality assurance and quality control activities.

TG100 references the Institute for Safe Medical Practices (ISMP) list of quality management tools. This list is sorted by effectiveness so that the lower numbers indicate more effective quality management tools. Considered the most effective are forcing functions: creating interlocks or barriers to literally force the user to follow another pathway such that the potential cause is removed. The next is: introducing automation into a process as any kind of manual entry is error prone. This can be achieved through: bar codes, automated monitoring, computerized verification and computerized order entry. Next on the list is: protocols, standards and information. It is considered to be of intermediate effectiveness to institute: check-off forms, clear protocols, alarms, labels, signs and to reduce similarity. Moving down the list is: independent double check systems and other redundancies such as redundant measurements, independent reviews, operational checks, comparison with standards, increase monitoring, status checks or acceptance tests. Next is rules and policies that establish: priority, communication lines, staffing levels, scheduling, mandatory pauses, repair, PMIs and other QC and QA work. And lastly, there is the option of providing education and information to staff.

TABLE III. Ranking of QM tools based on the effectiveness with examples, in part following the suggestions of ISMP (Ref. 67). The lower numbers are the most effective.

1. Forcing functions and constraints
   - Interlock
   - Barriers
   - Computerized order entry with feedback

2. Automation and computerization
   - Bar codes
   - Automated monitoring
   - Computerized verification
   - Computerized order entry

3. Protocols, standards, and information
   - Check-off forms
   - Establishing protocol/clarify protocol
   - Alarms
   - Labels
   - Signs
   - Reduce similarity

4. Independent double check systems and other redundancies
   - Redundant measurement
   - Independent review
   - Operational checks
   - Comparison with standards
   - Increase monitoring
   - Add status check
   - Acceptance test

5. Rules and policies
   - Priority
   - Establishing/clarify communication line
   - Staffing
   - Better scheduling
   - Mandatory pauses
   - Repair
   - PMI (preventive maintenance inspection)
   - Establish and perform QC and QA (hardware and software)

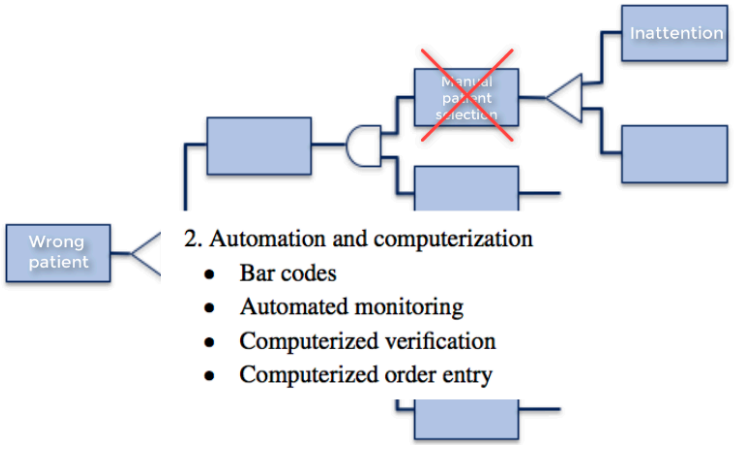
6. Education and information
   - Training
   - Experience
   - Instruction

The U.S. Department of Veteran Affairs National Center for Patient Safety also has a list of safety interventions that are ranked as stronger actions, intermediate actions and weaker actions. Some of the interventions are the same as in the previous list and are ranked similarly. Both lists are great resources in thinking of which quality activities are best suited to your potential failure pathway.

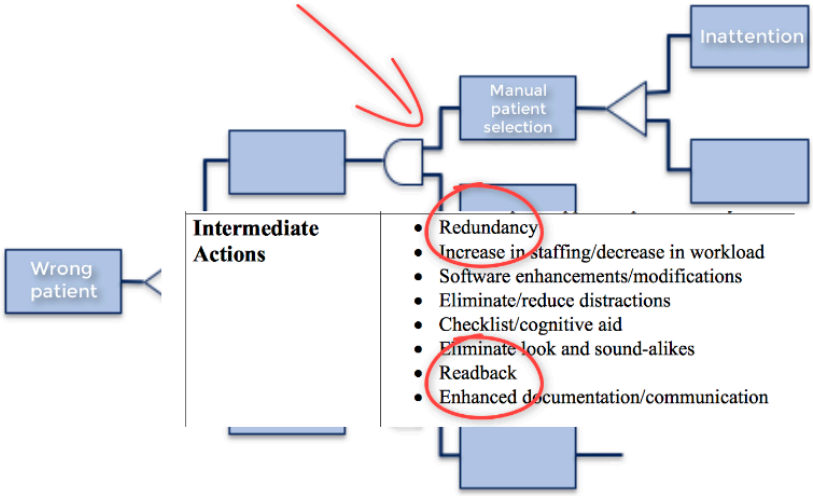
NCPS Patient Safety Intervention Hierarchy

Stronger Actions **(focused on system change, not reliant on individual memory/vigilance)**	• Architectural/physical plant changes • New devices with usability testing before purchasing • Engineering control or interlock (forcing functions) • Simplify the process and remove unnecessary steps • Standardize equipment on process or caremaps • Tangible involvement and action by leadership in support of patient safety
Intermediate Actions	• Redundancy • Increase in staffing/decrease in workload • Software enhancements/modifications • Eliminate/reduce distractions • Checklist/cognitive aid • Eliminate look and sound-alikes • Readback • Enhanced documentation/communication
Weaker Actions **(reliant on memory/vigilance)**	• Double checks • Warnings and labels • New procedure/memorandum/policy • Training • Additional study/analysis

Let's review an example: Let's assume I have identified a wrong patient failure in my clinic and my fault tree suggest that a potential pathway for this failure is due to manual patient selection and the underlying cause of manually selecting the wrong patient is due to inattention. The most effective intervention here would likely be to insert automation in the process of selecting the patient such that you can force a change in this failure pathway.



However, implementing automation can be cost-prohibitive and if this intervention is not possible, I may still choose from a number of intermediate actions such as redundancy or read-back so that I can add an additional AND gate to this FTA to reduce the likelihood of manually selecting the wrong patient.



And if those are not possible, I can still consider the use of training or double checks.

Do not be discouraged about choosing what are considered weaker actions. Sometimes an effective strategy is to solve several low-risk causes, those seen as an inconvenience to staff but those that lead individuals to cut corners. In medicine, errors often follow violations in protocols, particularly failures to perform verification procedures. Therefore, implementing something like standard operating procedures, together with regular training, can address several branches of a fault tree at once.

There are a couple of interventions that have been tried and are true in both radiation oncology and other disciplines including industry.

Checklists are a common intervention and if intelligently designed can be very effective. The following reference speaks to the power of checklists and provides guidance on their design even providing a checklist for checklists!

Fong de Los Santos et al., "Medical Physics Prac- tice Guideline 4.a: Development, implementation, use and maintenance of safety checklists," J. Appl. Clin. Med. Phys. 16, 37–59 (2015).

Reducing distractions

The airline industry has long understood the role distractions can play in failure pathways. The field of medicine is slowly mimicking these strategies by implementing no interruption zones, safe zones and quiet areas.

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Time Outs

The goal is to pause and review critical information before each patient procedure. Correct patient, correct procedure and correct site are the most critical. The Joint Commission even advocates getting the patient involved when possible. A routine time out in the context of radiation therapy is usually a pause immediately prior to the initiation of a radiation treatment. However, a time out can be inserted anytime or anywhere in the process. This allows staff to pause; to stop and think about critical parameters before proceeding with any part of the process.

And finally TG100 advises that any quality management program include a few key core requirements. These recommendations are not to be inserted directly into the failure pathway but rather can be implemented in small ways but systematically throughout each and every process, to lay the groundwork for a safer system. They are standardized procedures, adequate staffing and resources, adequate training of staff, maintenance of hardware and software systems and clear lines of communication.

TG100's Key Core Requirements

- Standardized procedures.
- Adequate staff, physical, and IT resources.
- Adequate training of staff.
- Maintenance of hardware and software resources.
- Clear lines of communication among staff.

It is difficult to know when considering all of these possible interventions where to allocate resources so a few things to remember: recognize that processes have higher failures than equipment, asses the highest risks and address them, think about effective PLACES in the process to insert quality activities, pay particular attention to common causes and be open to new approaches.

The goal is to design the "system". To support staff and equipment in order to prevent failures. To be resilient to failures. With the "system" consisting of equipment, staff, the patient and how everything interacts with each other.

Risk-based quality management is a very important aspect of quality and safety work in radiotherapy. But not the only one. A comprehensive approach to quality management includes both prospective and retrospective analysis of errors including incident learning. There are a number of excellent resources available as guidance on quality improvement and incident learning: the IAEA E-learning Course on Safety and Quality in Radiotherapy (http://elearning.iaea.org/m2/course/view.php?id=392) and the iTreat Safely videos (https://i.treatsafely.org/processcoach-qa-series/54933/qa/0) which are high-quality learning videos that deliver practical clinical and QA skills.

Realize that errors will take place. Our job is to do our best to prevent them, but more importantly, to keep errors from injuring patients.