This exhibit illustrates application of the A3 Lean Approach to solving a problem in a radiology department. The 8 subheadings are generic and can be applied to solving any problem.

Implementation of a Post-procedure CLOSEOUT to

Minimize Errors Following Completion of Interventional Procedures

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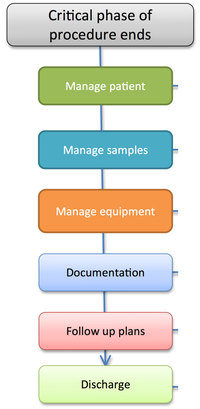
The A3 Lean Approach for Problem Solving in Radiology

PLAN

1. Reason for Action

- Over the last 3 years, a series of 8 seemingly unrelated adverse events occurred after the critical stage of IR procedures and were reported into our Patient Safety Reporting System.
- While each event was investigated and managed appropriately, a broader analysis allowed us to identify and categorize a trend and thus to implement a necessary Practice Quality Improvement project.
- We chose to use the A3 Lean format coupled with the PDCA cycle to root cause the problems, and to identify, implement, manage and monitor a series of countermeasures.
- This exhibit illustrates the practical use of the A3 Lean tool for problem solving specifically as it relates to post procedure adverse events.
- Of all the problems, why are we talking about this now?

2. Define the Current Condition or State



A representative team was established to clarify the current state, incidence, nature, severity and impact of the problem. No IRB approval was required since this was a necessary quality improvement investigation in response to reported adverse events.

To define the severity of the current state, all adverse events that impacted patient and staff safety and outcomes following completion of procedures were collected and analyzed.

The team undertook Gemba visits to all interventional suites to observe and document processes at the end of procedures. This allowed a standard process map to be developed.

Observation and chart audits were employed to document practice variations after procedures, as well as to document compliance with required procedure elements.

Our improvement goal was defined as complete absence of any adverse events after completion of procedures and the defined targets state was to develop and deploy the equivalent of the universal protocol ("time out") at the end of an interventional procedure.

3. Measures of Improvement

Based on data from the current state investigation, we defined our measures of improvement as follows:

- 100% compliance with performing closeout procedure with all elements included
- zero needle sticks following interventional procedures
- zero lost or mislabeled samples or wrong samples collected
- zero hardware left in patient
- 100% compliance with TJC documentation requirements and elements
- What is the specific chnage we want to accomplish now?

References

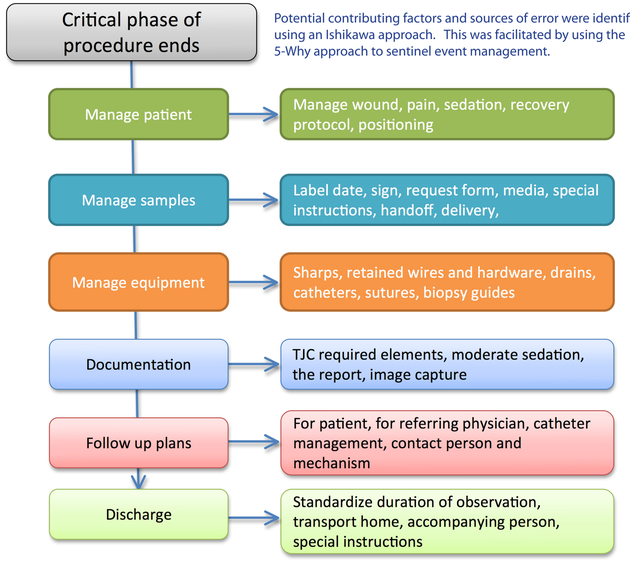
[1]Kruskal JB, Reedy A, Pascal L, Rosen MP, Boiselle PM. Quality initiatives: lean approach to improving performance and efficiency in a radiology department. Radiographics. 2012 Mar-Apr;32(2):573-87.

[2]Gemba visit - action of going to see the actual process, understand the work, ask questions, and learn (Jim Womack . Gemba Walks. Cambridge, MA: Lean Enterprise Institute; 2011)

4. Root Cause Analysis – *Why did things go wrong?*

We applied the basic tools of a root cause analysis to investigate each adverse event. A think tank group developed a standard process map for the post-procedure events.

1. Expand the process map to include putative contributing factors that take place after a procedure.
2. Use the 5-Why approach to investigate possible root contributors to the specific adverse events that occurred.
3. Apply the Ishikawa categories (people, equipment, policies, process) to identify potential latent contributors to an adverse event.



Potential contributing factors and sources of error were identified using an Ishikawa approach. This was facilitated by using the 5-Why approach to sentinel event management.

The **5-Why's approach** shows that each of these steps in the post procedure phase has a series of required elements, can be audited, requires education and onboarding and are prone to process and procedure errors.

5-Why approach to root cause analysis

1. Why was the wrong sample sent to the lab?
No sample request form was available

2. Why was no form available?
It wasn't printed off the computer order entry site?

3. Why was it not printed?
Nobody was asked or responsible for doing this

4. Why was nobody assigned responsibility?
It wasn't discussed during the pre-procedure timeout

5. Why was this not discussed during the timeout?
The process and content of our timeout procedures vary

Here is one big opportunity for improvement

This 5-Why approach showed that the focus was on pre-procedure content and verification, with no final check opportunities to close loops after procedures end. Consider alternatives

(For more detailed information on how to perform a root cause analysis, please see our exhibit **"Something went very wrong – a Practical Approach to Performing a Root Cause Analysis"**)

DO

5. Ideal Target Condition

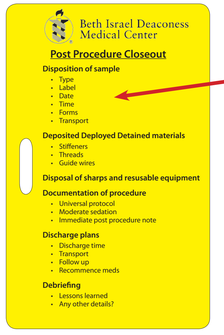
When undertaking a practice quality improvement project, it is essential to define the ideal target so that the gap between current state and target can be defined, and improvement options instituted. A target must be identified in order to define precisely how the gap will be closed.

For this post procedure practice quality improvement (PQI) project, we defined the ideal target as:

- No documented adverse events following any interventional procedure
- 100% compliance with post-procedure documentation and regulatory requirements
- Proper onboarding of all new staff and trainees specific to post procedure events
- Dissemination of the identified solution(s) to other clinical departments

What would we like to achieve with this effort? What can we do now? What options can we include that use creativity before capital? Have we considered alternatives? What can we expect from this effort?

6. Countermeasure Implementation Plan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Post Procedure Closeout

Disposition of sample
- Type
- Label
- Date
- Time
- Forms
- Transport

Deposited Deployed Detained materials
- Stiffeners
- Threads
- Guide wires

Disposal of sharps and resusable equipment

Documentation of procedure
- Universal protocol
- Moderate sedation
- Immediate post procedure note

Discharge plans
- Discharge time
- Transport
- Follow up
- Recommence meds

Debriefing
- Lessons learned
- Any other details?

We chose to develop the equivalent of the pre-procedure timeout that occurs after the critical phase of a procedure, a so-called Post-Procedure Closeout.
The elements of the closeout were defined as the 6 D's.

We considered possible constraints to the process:
- Educating our staff, including techs and nurses
- Onboarding new staff each year
- Changes in national patient safety goal mandates

Who will do this? What will be done? When will this start? What activities will be required and who will be responsible for what and by when? What might the impact of these changes be? Who will manage change? How will change be managed?

Lanyard cards were produced, training undertaken at the section level and the process communicated via a Quality Grand Rounds presentation, via e-mail and to each sections quality director. We included nursing staff, new trainee onboarding and technologists in the process.

We **considered possible constraints** to the process.

STUDY

7. Monitor Results and Processes

In the 15 months since implementation of the closeout procedure, we have seen:

- No needle sticks occurring after procedures
- No lost, incorrect or mislabeled samples
- No retained hardware or guide wires
- 100% compliance with the JC required documentation elements

How will we know if the actions have the desired impact? What remaining issues can be anticipated? When and how will this be followed up?

ADJUST

8. Standardize and Spread Processes

In accordance with the standard A3 lean approach, the process has been continuously improved and standardized:

- All members of the procedure team participate
- The closeout is run by the responsible staff radiologist while present in the room
- We have spread the process to all interventional services in our department
- We have shared the process with other hospital-based non-operative interventional services
- We are sharing this success story with our radiology colleagues via this exhibit

What components of our work have we standardized? Where will we spread this new standard next? Can this be spread beyond our department? How will we share the learning with our colleagues?