



Virginia Department of
Behavioral Health &
Developmental Services

Root Cause Analysis (RCA) October 2020

**A presentation for DBHDS
Licensed Providers**

DBHDS Vision: A life of possibilities for all Virginians

Goals of the Presentation

- ✓ **What** is a RCA
- ✓ **When** is a RCA required
- ✓ **Why** a RCA policy
- ✓ **How** to conduct a RCA

The goals of this presentation are limited. Root Cause Analysis has long been used by health care organizations after adverse events and/or to determine how to improve processes. Internet searches provide numerous resources for information on RCAs.

The focus of this training is to assist with meeting the components of conducting an RCA pursuant to the DBHDS licensing regulations. While this presentation also includes some additional material which may be considered best practice for an RCA, these are not required by the regulations. The presentation also highlights a couple approaches to conducting an RCA but additional approaches are available from other resources. Some additional resources are listed at the conclusion of this presentation.

Root Cause Analysis – What is it?

Reference – 12VAC35-105-20. Definitions:

“Root cause analysis means a method of problem solving designed to identify the underlying causes of a problem. The focus of a root cause analysis is on systems, processes, and outcomes that require change to reduce the risk of harm.”

An RCA is considered to be a standard quality improvement tool (per regulation). So you are using this tool to improve processes and systems in order to mitigate or reduce the risk of harm.

The purpose of an RCA is to identify system vulnerabilities so that they can be eliminated or mitigated. While licensing regulations require RCAs, licensed providers should consider the process as a best practice for improving outcomes. A root cause analysis is a tool for a provider to use when determining where they might focus their quality improvement efforts in terms of developing quality improvement initiatives. For example, a provider wants to reduce medication errors so the RCA could be utilized to get at the root cause (or causes) which you want to address through a quality improvement initiative. There are other tools for identifying quality improvement opportunities such as a Failure, Mode and Effects Analysis.

A RCA focuses on system, processes, and outcomes. It does not focus on people. While the process involves analyzing who did what, it is for purposes of looking for systems and process problems, not personnel problems.

Finally, a root cause analysis is about taking action.

Root Cause Analysis – The Focus

The focus of a Root Cause Analysis is on prevention, not blame or punishment.

A root cause analysis begins with the assumption that no one comes to work intending to make a mistake or to hurt someone. As noted in the best selling book of 1999, To Err is Human; Building A Safer Health System, people make mistakes but awareness of medical errors is important in terms of improving systems. To develop a culture of safety, staff should be encouraged to report errors without fear of retribution and to look for ways to improve systems.

That's not to say that a root cause analysis never uncovers intentional acts of harm. That may happen and when it does, you must take the appropriate action.

Root Cause Analysis – When is it required?

12VAC35-105-160.E

A root cause analysis shall be conducted by the provider within 30 days of discovery of Level II serious incidents and any Level III serious incidents that occur during the provision of service or on the provider's premises.

As noted earlier, a RCA should not be limited to just Level II or Level III serious incidents but this is what the regulations require. Providers are encouraged to think about always improving processes and outcomes and that involves looking for root causes to address.

Per the incident reporting guidance, "during the provision of service" means when the provider is actively providing a service to the individual.

12VAC35-105-160.E.

- 1. The root cause analysis shall include at least the following information:**
 - a. a detailed description of what happened;**
 - b. an analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider; and**
 - c. identified solutions to mitigate its reoccurrence and future risk of harm when applicable.**

The regulations establish the minimum requirements. Each provider's policy will further determine when more is needed.

Root Cause Analysis – Minimum Requirements

a. A detailed description of what happened.

- Step-by-step sequence of events leading up to an incident
- Actions taken immediately following the incident



Begin by making sure all three minimum requirements are covered.

- A detailed description of what happened – A provider can start with the incident report which provides date, time, place, individuals involved, a description of what happened. This could include what immediate actions were taken. This initial sequence of events helps identify what occurred. Often it is a chain of events that resulted in an incident.
- If more than one staff member was involved, each staff member could write what happened from their perspective. It is possible that others may have seen something even if they were not directly involved in the incident (i.e. they saw something from the window).

Root Cause Analysis – Minimum Requirements

b. An analysis of why it happened; including identification of underlying causes that were under the control of the provider; and

This second minimum requirement is where the work begins.

1. Compare what happened to what should have happened before, during and after the incident.
2. Compare actions taken before, during and after the incident to the requirements in the provider's policies and procedures, DBHDS licensing and other applicable regulations, accreditation standards and applicable laws.
3. Clearly identify the underlying causes of the incident that were under the control of the provider.

The “why” here is important. Based on the incident you could complete a “5 Whys” approach.

Root Cause Analysis – Minimum Requirements

c. Identified solutions to mitigate its reoccurrence and future risk of harm when applicable.

The whole purpose of an RCA is to prevent reoccurrence. The question is “what should we do to prevent this in the future?” **not** “What should we have done to prevent this from having occurred?”

Mitigating future risk is the most important question providers can ask as a part of their incident reporting, risk management, and quality improvement process.

The RCA should identify solutions, as applicable, to be taken by the provider to keep the situation from occurring again or minimize the likelihood of its reoccurrence and future risk of harm when applicable. Then the identified solutions to mitigate its reoccurrence should be implemented.

These solutions should be both individual-specific and systemic as indicated by the analysis of the incident. Implementation of solutions and their efficacy could be monitored as part of the provider’s quality improvement program.

12VAC35-105-160.E.2

2. The provider shall develop and implement a root cause analysis policy for determining when a more detailed root cause analysis should be conducted, including:

- convening a team;
- collecting and analyzing data;
- mapping processes, and
- charting causal factors



RCA is really best practice. Providers should view root cause analysis as an opportunity to address systems issues on an ongoing basis. The regulations, however, allow for some flexibility for when a provider completes a more detailed RCA.

RCA Policy

Specific to the organization

- size
- population served
- service specific
- criteria to use when determining the need for more detailed RCA (who appoints the team)

Policy shall include:

Minimum requirements from the regulations

DBHDS has made changes to provide greater clarity relating to when a provider should conduct a more detailed root cause analysis.

The incident management and root cause analysis components of this regulatory action are at the heart of the department's efforts to fully comply with the Settlement Agreement's quality and risk management provisions. In the time since the emergency regulation became effective, the department has issued additional guidance related to what constitutes "during the provision of services."

A provider's RCA policy should be specific to the organization. Consider size, population served; make it service specific, outline the criteria to use when determining the need for the more detailed RCA. The policy could outline who will appoint a team if a more detailed RCA is being conducted. The only requirement is that the policy include the minimum requirements outlined in the regulations.

12VAC35-105.E.2

At a minimum, the policy shall require a provider to conduct a more detailed root cause analysis:

a. A threshold number, as specified in the provider's policy based on the provider's size, number of locations, service type, number of individuals served, and the unique needs of the individuals served by the provider, of similar Level II serious incidents occur to the same individual or at the same location within a six-month period;

The regulations set some minimum standards....

Minimum Requirements

b. Two or more of the same Level III serious incidents occur to the same individual or at the same location within a six-month period;



Minimum Requirements

c. A threshold number, as specified in the provider's policy based on the provider's size, number of locations, service type, number of individuals served, and the unique needs of the individuals served by the provider, of similar Level II or Level III serious incidents occur across all of the provider's locations within a six-month period; or

Minimum Requirements

d. A death occurs as a result of an acute medical event that was not expected in advance or based on a person's known medical condition.

Example – More Detailed RCA

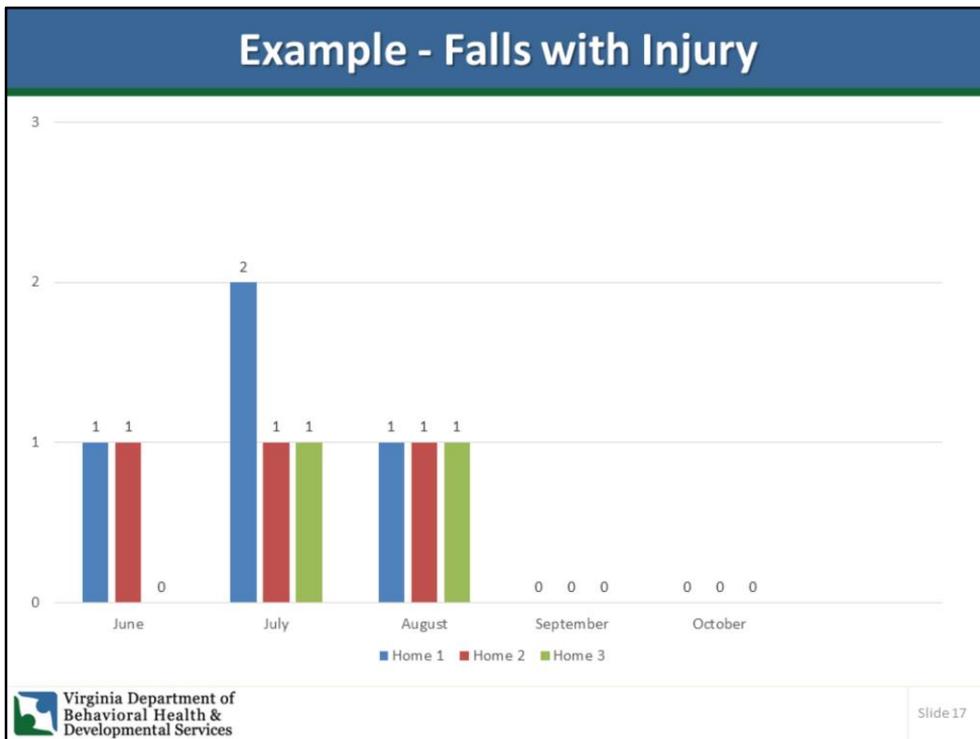
A licensed provider (named XYZ Residential) has three residential homes.

XYZ Residential's RCA policy states that a more detailed RCA will be conducted whenever 5 similar Level II serious incidents occur within a six-month time period across all three locations.



Every provider will need to determine (by its policy) the minimum thresholds.

So the following example provides a starting point.



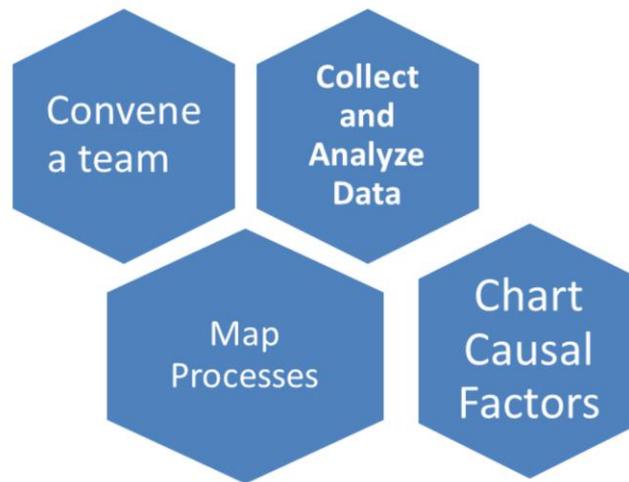
This is the data related to falls with injury for our example of XYZ Residential. Based on their policy (previous slide) would a more detailed RCA be required?

Some might quickly say “no - because actually their falls with serious injury declined (in September and October there were none).”

The provider’s policy, however, required a more detailed RCA when 5 similar Level II serious incidents occur within a six month time period across all three locations.

But, they shouldn’t be waiting for 6 month time period, the provider met the threshold outlined in their policy in July. There were two falls in June and four falls in July so they had six falls in two months (across all locations).

What is a More Detailed RCA?



A more detailed RCA is outlined in the regulations as including - convening a team, collecting and analyzing data, mapping processes, and charting causal factors.

Map processes – flow chart, storyboards, process maps, etc.

Causal factors – causal factor can be defined as any “major unplanned, unintended contributor to an incident (a negative event or undesirable condition), that if eliminated would have either prevented the occurrence of the incident or reduced its severity or frequency.”

Convene a Team

- **Provider's policy identifies who will appoint the team**
- **No requirements for how large a team must be**
- **Person responsible for risk management function (per regulation) has training in RCA so:**
 - **Lead the team or**
 - **Give overview/guidance**



In the example provided, XYZ Residential would begin by convening a team. It doesn't have to be a large team. In most cases, a RCA team may consist of 4-5 people and would be interdisciplinary. Different professional backgrounds can support creative thinking. The team members should be given a quick overview of what a RCA is and what it is not. Review rules of behavior (i.e. not about blame). Avoid hindsight bias (Monday morning quarterback). Teams can jump to conclusions so need to follow outline of how to effectively conduct a RCA.

The licensing regulations also require that providers designate a person responsible for the risk management function who has training and expertise in conducting investigations, root cause analysis, and data analysis. Depending on the incident and the organization, this person (the designated risk manager) may serve as the lead on the RCA team or provide guidance and an overview of the team's charter.

Do you include employees who were involved in the incident if conducting an RCA related to an adverse event?

In order to understand what happened and why it happened, it is necessary to talk openly during the team meetings about the actions of those individuals immediately involved in the event. Therefore the RCA literature states that the disadvantages of including involved staff outweigh the benefits. Reasons included:

- If they were involved, other team members may refrain from speaking up or be

hesitant to say something that might offend those involved.

- Likewise, those involved in the event may actually be overly harsh when judging their own actions
- It is less likely that those involved may steer the team from looking deeply into area that they feel will not reflect well on them individually.

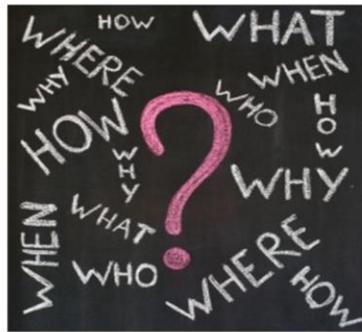
The involved staff can and should be interviewed. It is helpful to understand what actions they think should be implemented to prevent a reoccurrence of the event, but they should not be the ultimate decision makers of the official output of the RCA team.

Collect and Analyze Data

For the example outlined, XYZ Residential has identified falls with serious injuries. The RCA team would want to analyze the incidents:

- By home
- By day of the week
- By time of day
- By location (bathroom, sidewalk)
- By diagnosis of individuals involved (medication changes, vision exams, falls assessments)
- By weather conditions
- Other factors

Gather More Facts



Interview Those Involved

Find out what happened from the perspective of the person or people involved (frontline staff).

How many people you interview depends on the nature and the seriousness of the event(s). If looking at multiple events, it may require several interviews. If an event involved many people, you want to interview all of them but an event that involves only one person may only require you to interview that person. Remember to interview the individual involved in the incident if appropriate.

Use triggering questions and open ended questions.

When you interview, remember that this is not a criminal investigation and you're not looking to determine if someone was at fault – you are looking for the facts in order to solve a problem. Don't put the person you're interviewing on the defensive.

You want the people you are interviewing to feel safe so they will tell you everything they know.

You want to ask questions in a manner that helps them to remember the details because in a root cause analysis, the details matter.

Interviews Matter

Ask the person being interviewed to:

- Form a mental image of event
- Remember & report every detail of setting & people
- Describe what they remember; in their own words

Don't:

- Interrupt the person's train of thought
- Be confrontational or threatening

Your role is to identify causes, not to lay blame.

Interviews are to help people remember incidents. When possible, use open ended questions.

What Should Have Happened?

Compare Actions to Policies and Procedures



The next step is to compare what happened to what should have happened – before, during and after the incident. Compare the actions taken to the requirements in policies, procedures, regulations, accreditation standards, or laws. Why didn't staff follow the procedure?

Your intent here is not to find blame with someone for not following policies and procedures, or for doing something incorrectly. You are simply establishing the facts.

It is possible that everyone responded according to policies and procedures.

It's also possible that there were no policies and procedures to follow.

What Do Experts Say?

Review Literature



While licensing regulations do not require that a RCA include a review of best practices or literature, that is often a best practice recommended by performance improvement organizations. In our example, fall prevention literature may wish to be reviewed (an example would include resources provided by the DBHDS Office of Integrated Health).

Do I have the Root Cause?

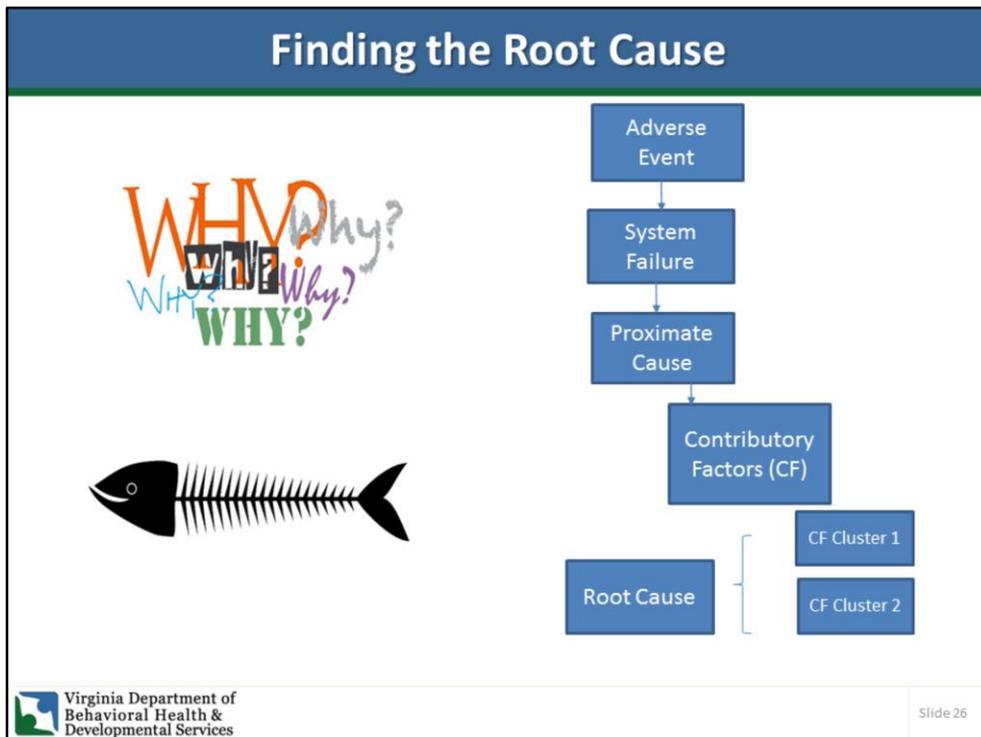
NO!

**Now you only have enough
information to state the
problem.**

Now you know what happened and what should have happened and this is where most people are inclined to stop. They know what the policy and procedures said should have happened, they know what was done and they think they have the answer or, more often, the person responsible. But that is not the root cause.

Remember, we are not looking for someone to take blame, we are looking for systems problems that create situations that lead to serious incidents.

Now you must state the problem and try to identify the root cause.



There are many ways to determine the root cause. Some are very detailed and complex but they all focus on one simple approach – asking questions.

Sakichi Toyoda, one of the fathers of the Japanese industrial revolution, developed the 5 Whys technique in the 1930s. He was an industrialist, inventor and founder of Toyota Industries. His method became popular in the 1970s, and Toyota still uses it to solve problems today.

Another approach is using the Fishbone Tool which is a visual way to look at cause and effect.

Another approach is called a contributory factors diagram. It is to establish a hierarchy, with the system failure at the top, followed by the proximate cause, followed by the categories of contributory factors – rank ordered. This approach can be done with post-it notes or index cards and the goal is to visually depict all of the major variables related to the issue and how those variables relate to one another.

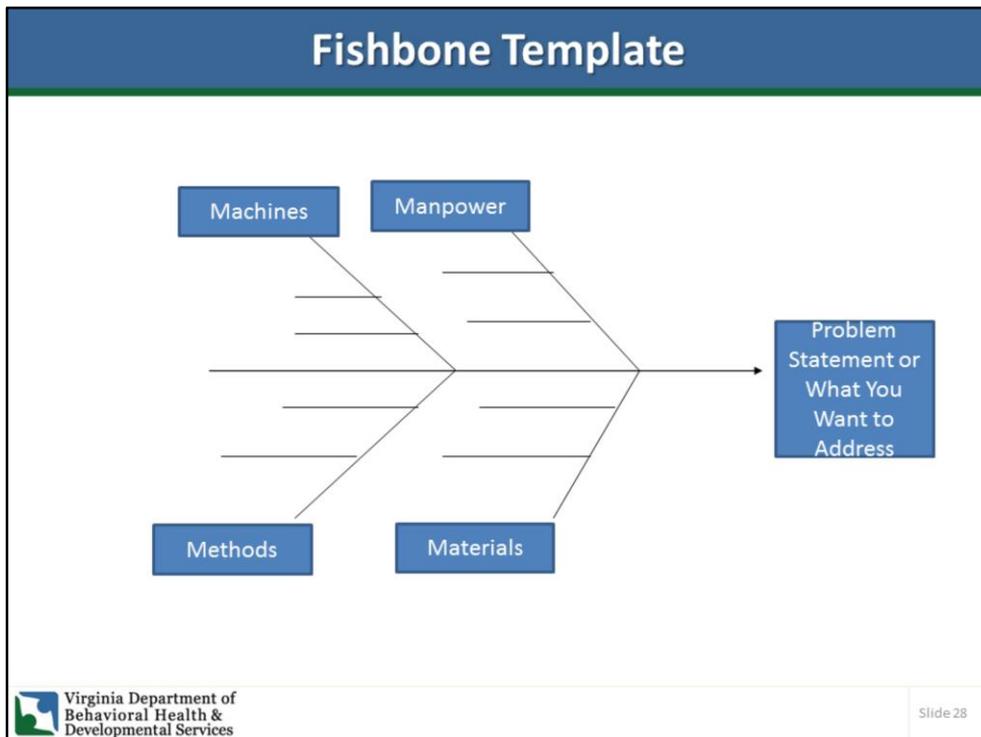
5 Whys Worksheet	
Problem Statement	One sentence description of incident, injury or problem:
Why?	→
Root Cause(s)	To validate root causes, ask the following: If you removed this root cause, would this event or problem have been prevented?


 Virginia Department of Behavioral Health & Developmental Services
 Slide 27

This sample worksheet from the Centers for Medicare and Medicaid Services (CMS) presents a format for documenting the 5 Whys.

The problem statement is a one sentence description of the serious incident. Then the series of “Why” questions are documented.

The hyperlink to this resource is listed on the final slide of this presentation.



Fill in your problem statement or what you want to address. Now think of possible causes in each category.

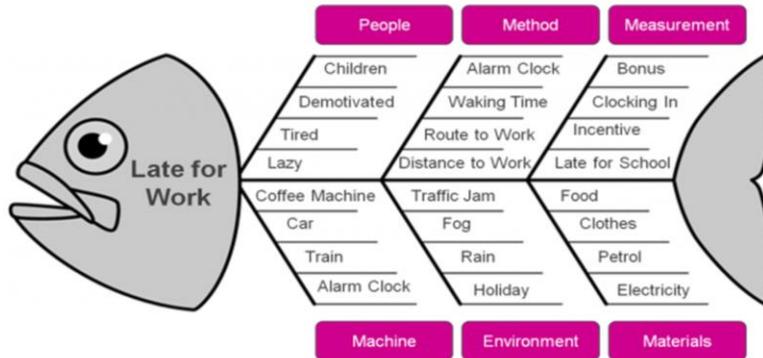
- Lack of policy/procedures (might be included in the methods category)
- Lack of training (might be included in the manpower bone)
- Not enough equipment (perhaps include under Machines)
- Staff shortages (manpower)

They can become the bones on this fish.

The hyperlink to the CMS template for a fishbone is also included at the end of this presentation.

Fishbone Example

Clip Art Example:



This Clip Art example shows the problem statement as being late for work. The causes included people (children missed bus); method (alarm clock didn't go off), measurement (clocking in); machine (coffee machine broke); environment (fog slowed traffic); materials (clothes at dry cleaners).

5 Whys Approach

XYZ Residential took the following steps:

- Appointed the RCA team
- Team reviewed data (falls by individual, time of day)
- Team evaluated equipment and location of falls
- Team interviewed various staff members
- Team members reviewed best practices (fall assessments)
- Team reviewed their policies and procedures

Using our example, XYZ Residential conducted a more detailed root cause analysis. They appointed a team (doesn't have to be a large group) They reviewed data.... They could divide these duties and then discuss as a team.

After they did all of that, they identified the problem statement – falls are increasing in the bathrooms. Based on that problem statement, they may need to interview more people (e.g. staff responsible for cleaning the bathrooms).

The team then asks Why?

5 Whys Approach

Problem Statement – Falls resulting in serious injury are occurring in the bathroom

Why are more falls occurring in the bathroom?

The staff report that the floor is often slippery when individuals step out of the shower.

Why is the floor more slippery?

The staff observed that the floor looks dirty or has a residue.

Why is the floor dirty or appear with a residue?

The cleaning agent is leaving a residue that results in condensation or slippery conditions especially in warm weather.

Why did the home switch to this cleaning agent?

The home did not switch cleaning agents, but the manufacturer altered their product and the home was not aware. The product label said “new and improved” but no longer included chemicals that added grip and resistance to the linoleum flooring.

XYZ Residential decided to use the 5 Whys approach.

Root Cause

The team identified a potential root cause using “4 Whys” (sometimes it will take more).

Slippery Floors Caused by Cleaning Solution = Falls



The team could say they identified the potential root cause using 4 Whys. There is nothing magical about 5 – could take 4 or 7.

5 Whys – Next Steps

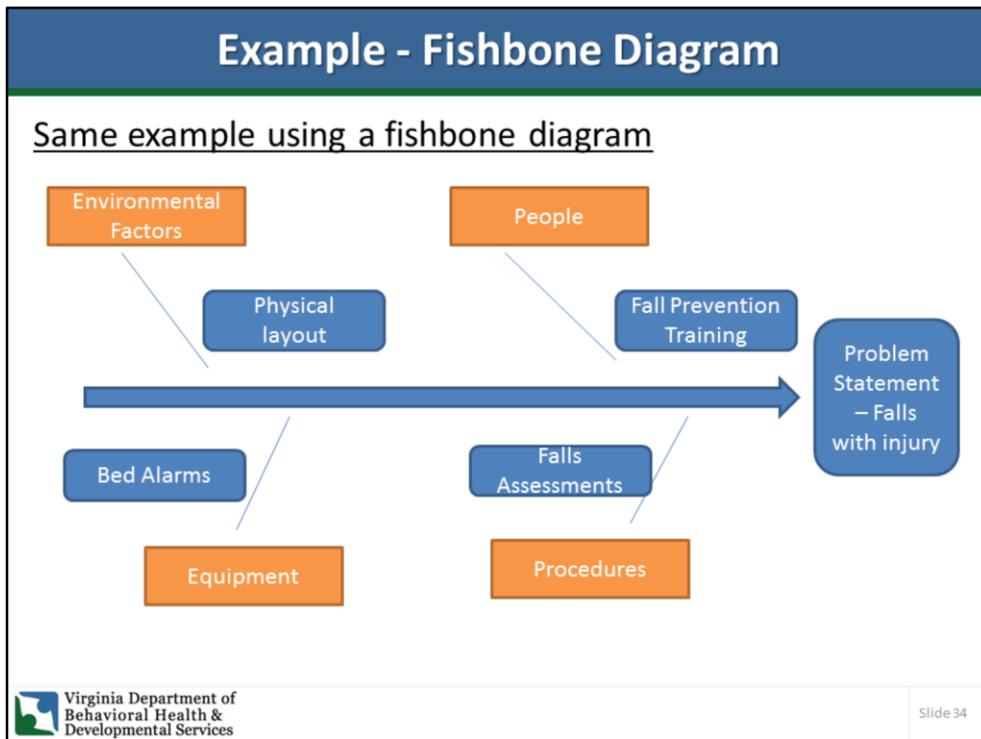
Now they need to **act** by recommending solutions to mitigate future incidents (falls in the bathroom):

1. Identify a new cleaning product that is “slip resistant”
2. Research anti-slip mats or other bathroom floor solutions to avoid slips, trips and falls
3. Follow the provider’s own processes (PDSA) to determine if they addressed the problem

Perhaps there were more root causes?

Does replacing the cleaning product mitigate harm?

This is how Quality Improvement/Risk Management/RCA all come together as it is a continuous process. The provider should continue to monitor falls; review their data (trends); communicate with staff regarding the change and then get their feedback (frontline employees may tell you that the floors are still slippery), etc.



The fishbone diagram can help identify possible causes by sorting ideas into useful categories. For example, this visual approach begins by drawing the head of the fish or mouth of the fish and identifying the problem statement. By writing the problem statement (i.e. increase in falls with injury), the RCA team members have a visual reminder of keeping their focus on the problem.

The team conducting the RCA would draw the major categories or causes of the problem. Some examples of major categories (or bigger bones of the fish) are indicated in orange. The smaller bones (indicated in blue) would be possible considerations.

Other considerations could include:

Environmental factors –

- adequate lighting
- bathroom access

People –

- turnover
- overtime/staff fatigue
- fall prevention training

Equipment –

- hoist lifts
- bed alarms

Procedures –

- falls risk assessments
- bathing protocols

You can draw the diagram on a white board and brainstorm with team members on all the possible causes. The final “bones” on the fish are then listed under each category. You may find that there are several causal factors under each category.

The value of using a fishbone is to dig deeper and ask questions about systems and processes that contribute to the problem.

Root Cause

The RCA team might determine:

- Majority of falls occurred due to environmental issue (visibility in bathrooms at night); or
- Medication changes were causing dizziness; or
- Fall protocols were not being updated and/or shared with employees.

One or Many Root Causes



In our example, the team may decide on one root cause, there may be more than one root cause especially since the falls were at three different homes and involved different people. In our “5 Whys” approach, the root cause may have been related to slippery floors but if the falls were found to be in different locations (bathroom, living room, on a sidewalk), then the root cause would be more than environmental issues. Perhaps the team would be looking at medication changes or fall protocol process.

Root Cause Analysis - Solutions

Developing an Action Plan:

- **Root cause/contributing factor statement**
- **Action**
- **Outcome measure**
- **Responsible person**
- **Management concurrence**

When the root cause is identified, the RCA team should identify what actions should be taken to mitigate reoccurrence. This includes identifying changes that again focus on systems. The provider may wish to change equipment or make an environmental change; simplify a process; implement a checklist. When doing so it is important to set an outcome measure as a means of determining the effectiveness of the change; who is responsible for implementing and making sure management is in concurrence with the suggested plan of action.

Quality Improvement Plan

Caution - Improvement requires change, but not every change is an improvement.



Organizations should always monitor to determine if the recommended actions resulted in mitigating reoccurrence and if the improvement is sustained.

In the example we used to show a 5 Whys and a fishbone approach, the team could identify a great new cleaning agent that helped prevent falls in the bathroom but it could result in another unrelated issue (allergic reaction) so you need to continue to monitor.

How will you know if change is an improvement? If you can't measure it, you can't prove it. Monitor the data to determine if change is an improvement, if there were any new issues identified, etc.

Solutions to Mitigate its Reoccurrence

Solutions ideally focus on systems rather than individual factors

- **Stronger actions**
 - Environmental changes – changing equipment, physical plant
 - Simplify processes – removing unnecessary steps
 - Engineering controls – equipment can only be connected in the correct way; bar coding for medication administration

Organizations often identify staff training as the solution, but stronger action are those that focus on systems. For example, utilizing automation.

Quality Improvement/Risk Management



This radial circle is to demonstrate the relationship to a central idea which is the health, safety and welfare of individuals served. The information in the outer ring of circles contributes to the central idea.

Root cause analysis as part of a risk management and quality improvement program ensures that systemic issues are being identified and addressed. It is one of many tools that can be used to support continuous quality improvement.

Continuous quality improvement is what every organization seeks - to make things better for people served. Providers can use RCA in several ways and through such use will become more proficient in the use of the tool. More importantly, the organization (and employees empowered to be change agents) will see the value in the process.

Resources

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/downloads/FiveWhys.pdf

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/downloads/FishboneRevised.pdf

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/ProcessToolFramework.pdf>

There are many resources online for how to complete a RCA. These are just those provided by CMS.