Root Cause Analysis (RCA)
The Basics

A presentation for DBHDS Licensed Providers

DBHDS Vision: A life of possibilities for all Virginians
The goals of this presentation are limited. Root Cause Analysis has long been used by health care organizations after adverse events. Internet searches provide numerous resources for more in-depth training.

The focus of this training is to assist with meeting the components of conducting an RCA as outlined in the DBHDS licensing regulations. While this presentation 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 a RCA but additional approaches are available from other resources. Some additional resources will be listed at the conclusion of this presentation.
An RCA is considered to be a standard quality improvement tool and acceptable per Licensing regulation. So you are using this tool to improve processes and systems in order to avoid future harm.

The purpose of an RCA is to identify system vulnerabilities so that they can be eliminated or mitigated. While licensing regulations require RCAs for Level II and Level III serious incidents, licensed providers should consider the process as a best practice for improving outcomes in other areas.

An 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.

Process means a group of activities that are related and organized and are repeated. Processes can lead to an output or they can achieve a certain goal. Examples of processes with which most people are familiar are the admissions process, the medication administration process, the person centered planning process, an individual’s personal care process, and the billing process. For each of these processes, there are certain steps you must take and there is an outcome.

Systems are complex sets of processes that involve many parts. Those parts may be activities or they may be mechanical. An example of a system is a provider payment
system, which will involve billing processes and reimbursement processes and coding processes. An example of a mechanical system is the heating/cooling system of your home, which has controls and thermostats, a heat pump, a furnace, fans and coils. A licensed provider has processes and systems.

Finally, a root cause analysis is about taking action. When the root cause of an incident is identified, it is critically important that action is taken to reduce the risk of the same or a similar incident occurring again in the future.
In the previous slide, it was noted that a Root Cause Analysis focuses on systems, processes and outcomes, not people. That’s important, because this process is not about placing blame or punishing people.

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.

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.
12VAC35-105-160.E

“A root cause analysis shall be conducted by the provider within 30 days of discovery for all Level II and Level III serious incidents”
While a previous slide identified when providers are required to complete an RCA by licensure regulation, providers should not be limited by that.
Root Cause Analysis

Is it ever appropriate not to complete a RCA for Level II or III serious incidents?

• No, a provider must document a detailed description of the event to the best of their knowledge, understanding if the incident did not occur within their services or on their property they may have limited knowledge of the incident;

• Provider should conduct an analysis of why the event occurred and note if a determination is made that potential underlying causes of the incident were not under the control of the provider;

• It is important to note that some level of analysis is required to determine whether or not the incident was under the control of the provider.

Situation most likely to occur with Level III serious incidents.
The point of an RCA is to address systemic causes for an incident; and to move away from a focus on individual factors (such as individual staff knowledge or competence; individual staff behaviors, etc.), and to avoid blaming or punishing staff even if an individual staff member may have forgotten to administer a medication or did not follow an established procedure. However, that does not mean that staff do not ever get disciplined for failure to follow policy, such as cases where they intentionally harm others; uses substances at work, breaks the law, etc. That does not mean that a provider could not look at whether there are any systemic factors that may have contributed to the failure to follow policy, or either supported, or failed to detect a staff member in continuing to engage in illegal or intentionally harmful behavior.

### Root Cause Analysis

**Focus – system, processes and outcomes; not people**

There may be situations however that staff will be disciplined.

Example - A serious incident is caused as a result of an intoxicated employee.

The provider would want to:
- Document what happened
- Determine whether there were underlying causes that were under the control of the provider.
- If identified, address those separately.
- Deal with the employee infraction through the Human Resources process
Root Cause Analysis
Licensing Minimum Requirements

12VAC35-105-160E.

The root cause analysis shall include at least the following information:

1. A detailed description of what happened
2. 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
3. Identified solutions to mitigate its reoccurrence
Begin by making sure all three minimum requirements are covered. Detailed description – what are the basics?

- 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.

- 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).
This second minimum requirement is where the work begins.

Licensing Guidance states that an analysis of why an incident occurred should:

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.
4. In the case of a Level III serious incident that did not occur while the individual was actively receiving services from the provider or on the provider’s premises, only be based on what is reported to or otherwise known by the provider.
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 processes.
It is important to determine who will conduct the RCA. As noted in the Guidance for Serious Incident Reporting, convening a team, collecting, and analyzing data, mapping processes, etc. may be considered based upon the circumstances of the incident.

If a team is convened, it doesn’t have to be a large team. If your organization is very small and it is impossible to convene a team, you can have a single employee conduct the root cause analysis. If you do this, that person should be a manager or supervisor who was not involved in the incident.

The 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 may serve as the lead on the RCA team.

Do you include employees who were involved in the incident?

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.

Best practice is that the team be interdisciplinary in nature with involvement of those knowledgeable about the processes involved in the event. Having team members with different backgrounds can also help support creative thinking.

But remember, it doesn’t have to be a large team or a team at all. This will vary according to the provider’s size and structure and the circumstances of the incident.
Find out what happened from the perspective of the person or people involved – the DSP who gave the wrong medication, the staff on duty when the power went out, the van driver who saw the person trip getting into the vehicle.

How many people you interview depends on the nature and the seriousness of the event. 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 and underlying causes 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 are to help people remember incidents. When possible, use open ended questions.

“What prevented you from assessing the patient’s risk of falls?” “What would have to change for that to work better for you?”
“What is another way you might be able to assure the skin assessment is complete?”
“Tell me how the individual fell.”
• Open and inviting
• Provides direction
  – “What prevented you from asking to stop and check?”
• Probing
• Gives the benefit of the doubt
“Tell me what your process is when there is a change in the individual’s condition.”
• Process oriented
  – “Help me understand what was happening while you were setting up your medications.”
• Clarifying
• Chance to explain
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.
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.
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.
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. Both approaches are accepted quality improvement tools.
Example – Level II Incident

There were several individuals waiting in the outpatient lobby. All individuals were watching TV. Sarah entered the area and became agitated saying “the TV is too loud.” Sarah looked for the TV remote and began asking other individuals about the remote. Sarah began pacing and became agitated. Bill told Sarah they didn’t have the remote and to sit down. Given the number of individuals waiting, there were few chairs available.

Bill told Sarah to be quiet. Bill got up from his chair and Sarah tried to sit in his chair. The two individuals started pushing each other. Sarah fell and broke her ring finger.

This example would be considered a Level II incident per Licensing Regulations and would therefore require a Root Cause Analysis.

A root cause analysis will be demonstrated using both the 5 Whys and the Fishbone Diagram.
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.
When using the 5 Whys, begin by writing the problem statement. Then continue asking why.

**Example Using 5 Whys Approach**

**Problem Statement** – A fight occurred between two individuals in the outpatient lobby which resulted in an individual sustaining a serious injury.

**Why** did a fight occur?
Sarah became agitated because she said the TV was too loud.

**Why** was the TV too loud?
No one could adjust the volume.

**Why** couldn’t anyone adjust the volume?
The remote was not in the lobby area. The receptionist controls the remote.
Example Using 5 Whys Approach

When responding to the Why questions, it is suggested to stop and ask “if the most recent response were corrected, is it likely the problem would recur?”

Example:
If you were to keep the remote in the lobby available to all individuals, would this prevent a similar incident from occurring?

No. It actually could cause more incidents. So this may be a contributing factor, but not the root cause.
In this example, it took more than 5 Whys to find the root cause. In other situations, it could take less than 5.
Another process for determining the root cause is to use a fishbone diagram.

A cause and effect diagram, often called a “fishbone” diagram, can help in brainstorming to identify possible causes of a problem and in sorting ideas into useful categories.

A fishbone diagram is a visual way to look at cause and effect. It is a more structured approach than some other tools available for brainstorming causes of a problem (e.g., the Five Whys tool).

The problem or effect is displayed at the head or mouth of the fish. Possible contributing causes are listed on the smaller “bones” under various cause categories. A fishbone diagram can be helpful in identifying possible causes for a problem that might not otherwise be considered by directing the team to look at the categories and think of alternative causes. Include team members who have personal knowledge of the processes and systems involved in the problem or event to be investigated.
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. fight in outpatient lobby resulted in an individual breaking her finger), the RCA team members have a visual reminder of keeping their focus on the problem.

The team or individual conducting the RCA would draw the major categories of 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 –
- Was there adequate seating
- environment less conducive to violence (softer lighting)

People –
- training on how to identify the potential for violence, such as a determining whether someone is irritable, confused or threatening
  - language

Equipment –
- panic buttons
- alarms
- metal detectors

Procedures –
- policies on wait time

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.
When the root cause is identified, the RCA team or individual completing the RCA should identify what actions should be taken to mitigate reoccurrence. This includes identifying solutions 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.
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
Solutions to Mitigate its Reoccurrence

**Intermediate actions**
- Increase staff or decrease workloads
- Eliminate or reduce distractions
- Implement checklists
- Standardized communications
- Improved documentation

**Weaker actions**
- Double checks
- Write/implement new procedure/policy/memo
- Staff training
Quality Improvement Plan

Action plans from root cause analysis can become part of a provider’s quality improvement plan.

Caution – improvement requires change, but not every change is an improvement.

Organization should always monitor to determine if the recommended actions resulted in mitigating reoccurrence and the improvement is sustained.
One way to monitor is to follow a deliberate and defined improvement process. While there are many performance improvement models, Plan-Do-Study-Act, is one example of how to achieve measurable improvements.

**Plan** – identify and analyze the problem or opportunity, develop hypotheses about what the issue may be, and develop a plan to test, including a plan for collecting data

**Do** – test the potential solution, ideally on a small scale, and collect data

**Study** – analyze the results and compare them to your predictions; measure effectiveness, and decide whether the plan worked or not

**Act** – based on what is learned from the test, make a plan for another test or implement the solution if successful

**PDSA** is a systematic testing of possible solutions, assessing the results, and implementing those which are shown to be successful.
What Licensing Specialists will Look for During Inspections?

Proof that:

– Provider has a clearly documented process for when and how RCA will be conducted;
– Staff have been trained on how to complete a RCA;
– There is a completed RCA for each Level II and Level III serious incident;
– RCA clearly contains all required components;
– Changes are made as a result of RCA, as appropriate such as revised protocols or policies;
– If changes are not made, reasons why are clearly documented;
– Changes are clearly communicated to all staff at all levels; and
– Changes are monitored to ensure they are effective.
Summary

Licensed providers are encouraged to:

- Conduct RCAs in compliance with regulations
- Try different approaches for finding root causes (5 Whys or Fishbone Diagram)
- Make system changes based on the identified root cause(s)
- Sustain improvement(s) through monitoring and quality improvement plans
Many resources and trainings are available online.

Resources
