Office of Licensing

Frequently Asked Questions

12VAC35-105-160.E – Root Cause Analysis

1. **Are there specifications on what a "more detailed RCA" entails? What is a basic RCA?**
   12VAC35-105-160E.2 – The provider shall develop and implement a root cause analysis policy for determining when a more detailed root cause analysis, including convening a team, collecting and analyzing data, mapping processes, and chart causal factors, should be conducted.

   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.

2. **Why does the provider set the thresholds for a more detailed RCA?**
   The ability of providers to define their own thresholds is in recognition of the vast differences between providers based on their size, the number of individuals that they serve, and the type of services that they offer. While it is true that providers can raise these thresholds, it is anticipated that providers will adopt thresholds that are reasonable in relation to their unique circumstances and that the provider would recognize the importance of conducting a root cause analysis to understand why an adverse outcome occurred and how it can be prevented from happening in the future.

3. **What is a process map?**

   A process map is a quality improvement tool that graphically shows the inputs, actions and outputs of a process in a clear, step-by-step map of the process. By using a process map it is possible to identify challenges and how to improve processes.

4. **Where is a team required for a RCA?**
   A team is required for conducting a more detailed root cause analysis (12VAC35-160.E.2). Whether or not a team is required is provider/service specific and should be addressed by providers within their RCA policy. There is no requirement for the size of a RCA team.

5. **A provider has 30 days to complete a RCA, is there a timeline for when the team needs to convene and complete the analysis?**
   There is no regulatory requirement for when the team must convene to complete the RCA as long as the RCA is completed within the 30 days. Timeframes should be included within the provider's RCA policy which OL will review to see the provider followed their own policy. Best practice would certainly be to begin interviewing people and collecting information as soon as possible following an event or events that require a more detailed RCA.

6. **What is the correct job title for the person in charge of RCA?**
   The regulations do not require a specific title for the person in charge of conducting RCA. The provider's RCA policy might include specifics related to who conducts a RCA and/or who appoints a RCA team when a more detailed RCA is required pursuant to the provider's policy.
   The person designated as the risk manager has RCA training pursuant to 12VAC35-105-520.A so that person may lead the team or ensure that the team completes its work in compliance with the provider's policy.

7. **Would the person conducting these interviews for the RCA also be required to have certification such as needed for persons conducting investigations?**
   The only required risk management training are the training topics enumerated in 12VAC35-105-520.A. If staff are appointed to a RCA team and are asked to interview people regarding an incident, it is not necessary to have specific training. The person responsible for the risk management function who has training in RCA could help lead the team or provide information on how to ask questions. Providers should consider whether any additional training or certification would be helpful for their staff members with RM responsibilities.

8. **Should we include state system issues in our RCA process?**
   The RCA process is intended to identify the root cause(s) of specific incidents so that the provider can take appropriate steps to mitigate the risk that such incidents may recur. This process should include consideration of any circumstances/occurrences that the provider believes may have contributed to the incident at issue.

9. **Is this level of review expected for every single RCA or only certain ones?**
   The level of detail involved in a Root Cause Analysis is expected to vary based on, among other things, the specific thresholds specified in the provider's policies and procedures for triggering the requirement to conduct a more detailed RCA.

10. **Once a threshold has been met, how long do we have to complete our more detailed RCA?**
    RCAs shall be conducted within 30 days of the discovery of a Level II serious incident and any Level III serious incident that occurs during the provision of services, or on the provider's premises. When a threshold has been met requiring a more detailed RCA, the 30 day timeline for conducting the RCA remains the same. Therefore, the RCA should be conducted within 30 days of the occurrence of the incident that ultimately met the threshold.

11. **Explain the difference between the CHRIS investigations being required to be completed within 10 days of an incident and RCAs having 30 days. Seems investigations should be a part of RCAs.**
    A root cause analysis is not the same as an investigation. Investigations often focus on what happened and who may have been responsible. Root cause analysis is more about asking "why" and the focus is on systems factors. The Office of Human Rights regulations include timelines related to provider's completion of investigations of abuse/neglect and exploitation allegations. Provider can contact the local Office of Human Rights advocate if there are questions regarding these investigations.

12. **What if the events leading up to the incidents were outside of the control of the provider? If incidents occur that are not determined to not be within the control of the provider, is it acceptable to indicate this in the 5 Whys or indicate what we see as the actual root cause?** There may be situations where the events leading up to the incident were outside of the control of the provider. In completing the RCA, the provider should include all underlying causes that were under the control of the provider. The provider may still be able to identify solutions to mitigate the reoccurrence and future risk of harm, when applicable.

13. **Can the root cause analysis policy be part of the risk management policy?**
    Yes, one policy could cover the requirements of RCA (12VAC35-105-160.E.2) and risk management (12VAC35-105-520.B).

14. **Will Level II serious incidents of presumptive positive or lab confirmed diagnoses of COVID-19 be counted towards the DBHDS uniform thresholds for similar Level IIs for an individual, same location, and/or all locations for conducting the more detailed RCAs?**
    An Office of Licensing correspondence, dated January 14, 2021, addressed revised expectations related to required reporting of individuals diagnosed with COVID-19. The threshold numbers for conducting a more detailed root cause analysis are to be determined by the provider as part of the provider's Root Cause Analysis policy. A root cause analysis would be expected if multiple people in the same location were diagnosed with COVID-19 in order for the provider to determine what could be learned to prevent spread of COVID-19 as well as addressing any systemic issues related to infection control.

15. **Can a provider use the 5 Whys with sending someone with a MH condition to the ER for further assessment in an outpatient environment?**
    The 5 Whys technique for conducting a RCA can be used any time if that meets the provider's RCA policy. The 5 Whys technique assists in meeting the regulatory requirement of "an analysis of why it happened, including identification of all identifiable underlying causes of the incident under the control of the provider." (12VAC35-105-160.E.1.b)

    Five Whys Example –
    Why was an individual taken to the emergency room for an assessment?
    The individual presented with violent behavior toward himself and others in the outpatient clinic.
    Why was the individual presenting violent behavior toward himself and others in the outpatient clinic?
    The individual's medications had not been renewed and he was without medications.
    Why weren't the medications renewed?
    The medication was not renewed because it required lab results which had not been received.
    Why had the lab results not been received?
    The lab results were delayed because the lab sent the results via email to the individual who did not have access to emails rather than sending directly to the pharmacy.

16. **Do we have to do a more detailed root cause when we reach a threshold for unrelated, random deaths for Mental Health Case Management clients?**
RCAs are required only for level II serious incidents and level III serious incidents that occur during the provision of services or on the provider's property; so a more detailed RCA would be required for a death that occurs as a result of an acute medical event that was not expected in advance or based on the person's known medical condition only if the death occurred during the provision of services or on the provider's premises. If the MH case management service was not being provided, and the individuals were not on the provider's premises, then the RCA would not be required.

17. **What is your suggestion when a provider reaches a threshold across all localities and there is literally no root cause? For example, we get dozens of unexpected Emergency Room Visits. There is typically no trend or reason why these are occurring, they just occur frequently based on our population.**
As noted in 12VAC35-105-160.E.2, the provider's RCA policy would outline the threshold based on the unique needs of the individuals served. It is necessary to review incidents to attempt to identify possible trends which could lead to a root cause that could be mitigated. Root Cause Analysis and developing potential corrective actions are essential tools for making improvements through the provider's quality management program. RCA is a tool designed to help identify not only what and how an event occurred, but also why it happened. Only once it is determined why an event occurred, or in this situation a threshold number of similar events occur, will a provider be able to identify measures that may prevent or reduce the number of future similar events. It is only through the root cause analysis process that all the contributory factors can be identified.

18. **It would be helpful to have examples other than for developmental disability residential services. A lot of the regulation changes and requirements are clear for how they apply to residential settings, but are more challenging to apply to other services (for instance, outpatient clinic).**
Disclaimer: The examples provided below are for educational purposes only. Each provider's policy should outline provider specific thresholds based on the size, number of locations, number of individuals served and the unique needs of the individuals served.

In addition, the thresholds must meet all the minimum requirements included within 12VAC35-105-160.E.2.a-d:
a. "A threshold number, as specified by 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"

> Example – A partial hospitalization program at one (1) location serves 25 individuals. The provider's RCA policy states that when three (3) or more of the same Level II serious incidents occur to the same individual within a six (6) month period, the provider conducts a more detailed RCA. The provider reports a Level II serious incident regarding a missing person in May and then two Level II serious incidents involving missing persons in August. Based on the provider's RCA policy, a more detailed RCA is conducted because the threshold was met when three of the same Level II serious incidents occurred at the same location within six months. (*Missing means a circumstance in which an individual is not physically present when and where he should be and his

absence cannot be accounted for or explained by his supervision needs or pattern of behavior.)

Example – A supportive in-home provider for thirty (30) individuals with developmental disabilities has a RCA policy that states a more detailed RCA will be conducted when two (2) of similar Level II serious incidents occur to the same individual or at the same location within a six (6) month period.
The provider reports a Level II serious incident involving a fall with fracture in December, another individual sustains a fall with fracture in March. The provider conducts a more detailed RCA because their policy is that two similar incidents occur within six month period.

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"

Example – An Intensive in-home provider serving 50 individuals has a RCA policy that when 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, the provider will conduct a more detailed RCA.

The provider reports a Level III serious incident of a suicide attempt by an individual that results in hospital admission in March. In June the provider reports a Level III serious incident of a suicide attempt that results in hospital admission by the same individual. The provider conducts a more detailed RCA in accordance with the provider's policy.

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

Example - A supervised living residential service provider with three (3) locations serving 6-8 individuals per location has a policy that when three (3) similar Level II or Level III serious incidents occur across all of the provider's locations within a six month period, the provider will conduct a more detailed RCA. In July the provider reports a missing individual at Location A; in August, the provider reports a missing individual at Location B; in September, the provider reports a missing individual at Location A. The provider conducts a more detailed RCA in accordance with the provider's policy.

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 – A developmental services group home reports a death of an individual. The individual with no known medical conditions died of a massive heart attack. The provider's RCA policy requires a RCA for any death that 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 – An individual is receiving services at a substance abuse intensive outpatient location and during service the individual experiences a seizure and suddenly dies. The individual had no known medical conditions. The provider conducts a more detailed RCA because this was a Level III serious incident that was not expected in advance or based on the person's known medical condition.

19. **There is incident of alleged abuse and neglect that results in injury, we complete two CHRIS reports (one on the abuse side and one for the serious injury). The investigation is submitted for the alleged abuse, are we required to complete a RCA for the serious injury in this case?** Yes a RCA needs to be completed if it is a Level II serious incident. In this case if the incident is a serious injury. A serious injury is defined as any injury resulting in bodily hurt, damage, harm, or loss that requires medical attention by a licensed physician, doctor of osteopathic medicine, physician assistant, or nurse practitioner.

20. **It would be helpful to have an OL approved list of which incidents fall into this category so there is consistent application of regulation across specialists. And providers are clear as well.** A RCA must be completed for all Level II serious incidents and all Level III serious incidents which occur within the provision of services or on the provider's property. A RCA does not need to be conducted for Level I. Please remember that even when a root cause analysis is not required, the provider shall collect, maintain, and review at least quarterly all serious incidents, including Level I serious incidents, as part of the quality improvement program in accordance with12VAC35-105-620 to include an analysis of trends, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents.