
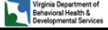


Risk Management and Quality Improvement Strategies

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Presented with VA DBHDS

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DBHDS Introduction

Completion of this training meets the requirements for risk managers to complete department approved training (12VAC35-105-520.A) with the exception of:

Training related to conducting investigations to be provided by the Office of Human Rights

DBHDS will post to Office of Licensing website

- Crosswalk of trainings
- Attestation regarding completion of training for 520A
 - Completed and signed by risk manager and supervisor
 - Attestation to be available upon request by Office of Licensing

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Context

The Commonwealth of Virginia must ensure a comprehensive quality and risk management system that:

- Requires that CSBs and other community providers of residential and day services implement risk management processes, including establishment of uniform risk triggers and thresholds that enable them to adequately address harms and risks of harm, including any physical injury, whether caused by abuse, neglect, or accidental causes;
- Offers guidance and training to providers on proactively identifying and addressing risks of harm, conducting root cause analysis, and developing and monitoring corrective actions;
- Requires providers to develop and implement a quality improvement program that is sufficient to identify and address significant service issues and is consistent with the requirements of licensing regulations;
- Requires providers to report on statewide performance measures that capture information regarding both positive and negative outcomes related to health and safety and community integration;

Today, we'll talk about how to develop and implement risk management processes that comply with these requirements, and that facilitate identifying and mitigating risks of harm, while establishing a culture of continuous quality improvement.

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Overview of Content

- Components of a comprehensive quality and risk management system
- Developing culture of continuous quality improvement
 - Understanding Human Error
- Risk Screening & Addressing risks of harm
- Incident Management & Risk Triggers
- Root Cause Analysis & Contributory Factor Analysis – Tools for systemic learning and prevention
- Data Measurement & Analysis
 - Using data to identify risk patterns and trends and inform quality improvement activities
- Developing systemic preventive strategies & corrective actions
- Access to training materials on today's topics

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Systems of Risk Management & Quality Improvement

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Components of a comprehensive quality and risk management system

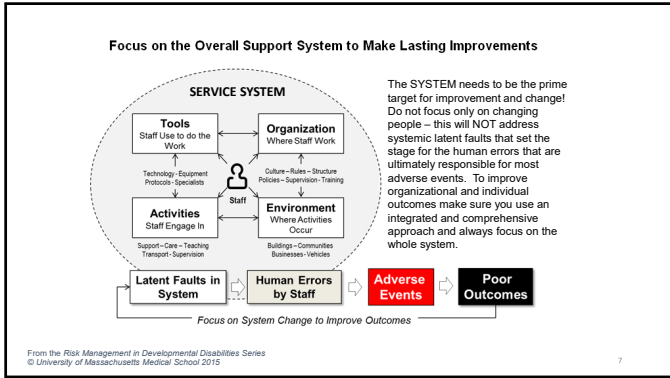
- Consider what methods and tools you currently use to track and monitor the quality of your services and the welfare and safety of the people you support, including:
 - Those required by regulation
 - Those added by your organization
- Some of the more common risk management and quality assurance methods and tools that are present in many provider systems include:
 - Case management and service coordination planning and oversight of supports
 - Abuse and neglect reporting and investigation systems
 - Complaint reporting and review systems
 - Insurance claim investigations
 - Incident reporting and review
 - Licensing and certification processes; provider contracting, program monitoring and site reviews
 - Accreditation reviews
 - National and/or statewide survey reviews (ex. NCI, QSRs)
 - The use of quality improvement targets and performance assessments

Step back and look at the Big Picture: How are these processes and tools integrated?
Are they effective?

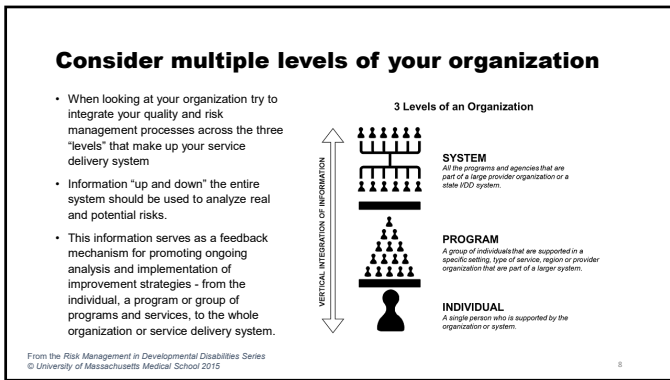
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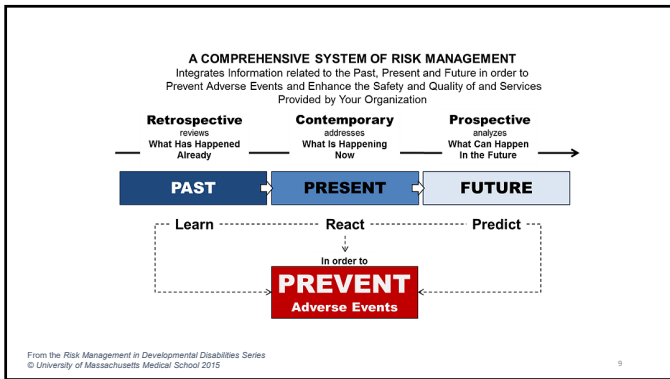
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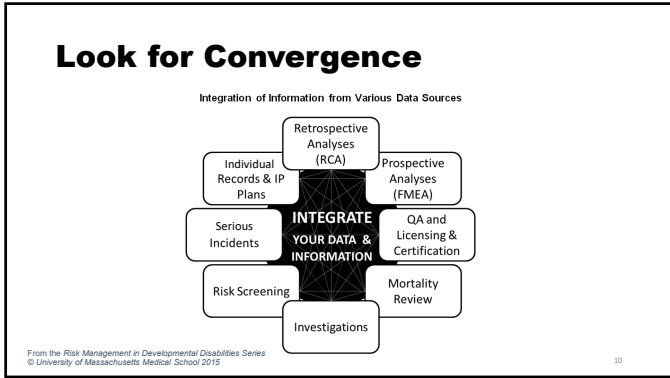
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- ### Important Considerations When Establishing a Comprehensive System
- Integrate Data
 - Review What Has Happened, Is Happening and Will Happen
 - Analyze Information about the Person, the Program and the Overall System
 - Establish a Strong Culture of Safety
 - Understand Why Adverse Events Happen
 - Use Structured Tools and Processes
 - Design a Comprehensive System of Risk Management
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A Culture of Continuous Quality Improvement

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What is culture?

- **Organizational Culture:** is the shared beliefs, values, attitudes, and behavior patterns that characterize the members of an organization
 - *Cultures are formed and sustained by what we DO*

What is a Culture of Quality?

- An environment in which employees not only follow quality guidelines but also consistently see others taking quality-focused actions, hear others talking about quality, and feel quality all around them.

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A Systems Perspective

- Consider the role of *human behavior* when evaluating risk and determining what actions you can take to help make your services and supports safer and better.
- A truly effective and comprehensive system of risk management requires an organization to step back and take a look at the *big picture* and envision how it can better integrate and enhance the utility of existing tools.

Remember: Every system is perfectly designed to generate the outcomes it yields.

- Want to change the outcomes? Change the system!

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Aspects of a Culture of Quality

- Be a learning organization
 - Strive to understand why errors happen
 - Move away from blaming staff for errors
- Measure –and share and use the information/data
- Encourage people to actively look for mistakes, STOP them before something bad happens
 - Reward finding problems and fixing them (not hiding problems)
 - Support reporting “near misses” and “close calls”
 - Identify issues early
- Build quality and safety systems into routines

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Consider the System's Role

- How did various components of your system set people up to succeed or fail?
 - Tools people use (protocols, policies, procedures and the materials and equipment that are provided by the organization)
 - Tasks and activities they engage in (that are scheduled, dictated and regulated by the organization)
 - Competing priorities or other stressors
 - Insufficient resources (staffing, equipment)
 - Insufficient knowledge or skills given to staff
 - Organizational culture, expectations, messaging from leadership

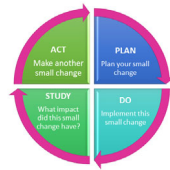
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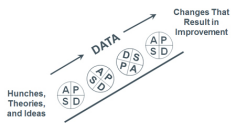
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Implementing Systemic Improvement: PDSA

The results of a strong problem analysis identify opportunities for systemic improvement that feed directly into the Continuous Quality Improvement cycle: Plan/Do/Study/Act



Use the PDSA cycle for one step at a time:

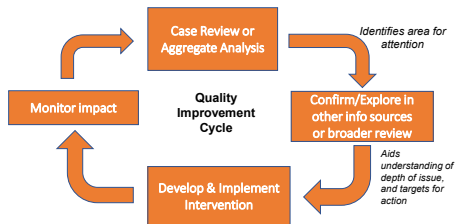


Source: The Improvement Guide p. 103

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Use of System's information in the Quality Improvement Cycle



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A Word on Compliance vs. QI

• If you meet all of your external compliance requirements, *does that mean the people you serve are experiencing optimal outcomes?*



- Compliance is *necessary* but *not sufficient*.

• In QI, organizations can thoughtfully determine what problems need to be addressed and prioritized.

- Particularly those problems that, if solved, would have substantial impact on peoples' lives.

• Avoid the "monitor-everything, but improve little" mindset

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Let's look at an example:

Compliance: Licensure/NCI

- Staff provide recreational programming (89%)
- People go out to eat in last month: (88%)
- People go out shopping in past month: (91%)

QI: Outcomes (NCI)

- Can choose how to spend free time (69%)
- Feels lonely sometimes or often (45%)
- Do you get to do the things you like to do as much as you'd like? (76%)
- Has friends (76%)

Components are Necessary....

But certainly not sufficient

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Example data-driven quality improvement projects

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Example: Injurious Falls

- **Issue:** Observed accidental deaths, particularly due to falls in **aggregate mortality analyses** of people with disabilities
 - Confirmed trend in analysis of reasons for ER visits: 41% of all reported ER visits for injuries were related to a fall
 - Benchmarked Falls Risk - higher than in the elderly in general population

} Convergence!

→ We've confirmed the problem, now what's the solution?

- We know that falls are connected – one fall heightens the risk of a future fall. Major injurious falls often have earlier falls without injuries. Whether a fall is injurious is largely due to chance.
- Few resources exist for falls in people with certain disabilities

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Example: Falls Prevention

Actions:

- Distributed training materials to all service providers with fall risk factors, universal prevention strategies, and risk assessment tools
- Piloted a multi-faceted falls prevention intervention focused on site and individual level factors, including post-fall review
 1. Baseline fall risk assessment used for people with learning disabilities to identify fall risk factors before a fall occurred
 2. Support workers were asked to track falls
 3. After each fall, support workers asked to complete Post-fall Assessment

Outcome/Improvement:

- Result: 33% reduction in the monthly rate of falls

Developed a Post-fall Assessment & Strategy Guide

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Example: Preventive Health Screenings among human service recipients

- Numerous incidents of death from these types of cancers, as well as late detection (due to symptoms rather than screening)
- Mammography: 59.6% of women with DD aged 40+ had a mammogram in previous year (in 2008 MA: 84.9% ; US:76%)
- Colorectal Screening: About 1 in 3 of adults with over age 50 ever had screening (in MA: 50% within 5 years).

Certain subgroups at highest risk for lack of screening:

- In a retrospective chart review¹ of women over age 40 with DD in a residential support setting:
 - Women needing special positioning 25 times less likely to have screening.
 - If able to give consent: 20 times more likely
- Women with less supports are at risk for missing or delayed screening.
 - Importance of support, informed health advocacy

Wilkinson JE, Laaser E, Freund KM, Rosen AK. (2011). Individual and system-level characteristics associated with mammography in women with intellectual disabilities. Journal of the American Board of Family Medicine. 23

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Understanding Human Error



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Culture of Safety

- Organization strives to reduce the risk of harm across all systems and at every level.
 - Requires partnerships with clinicians and provider agencies to build quality improvement approaches across a system
- Look beyond "fault" and try to really understand why errors take place
- Consider barriers and behaviors that inhibit safe practices and the establishment of a meaningful culture of safety within an organization
- Reporting culture – with trust as a required factor

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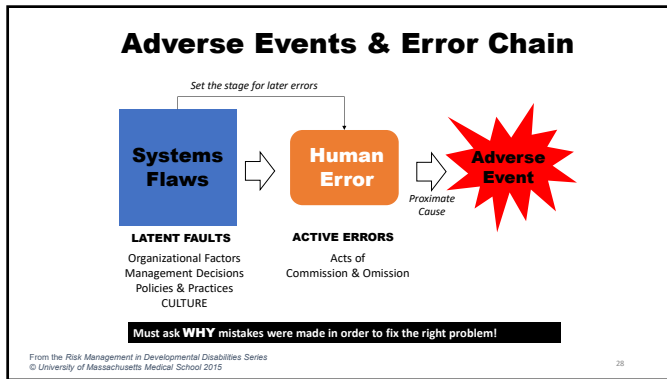
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Stop Blaming to achieve stronger systems

- Person-level approach: Punish the person who made a mistake; maintaining a punitive stance toward individual staff members
 - Disciplinary actions, corrective action, retraining, termination
- Systems-level approach: Leadership establishes an atmosphere where all staff recognize the importance of understanding why adverse events take place.
 - Recognize the role that managers and the organization play in setting the stage for errors, i.e., staff actions that can lead to bad things happening.
 - Learn from adverse events and work on preventing them in the future

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A word about Active Errors

Different reasons for errors that result in an adverse event. Must understand why the error took place. It's not always because of "bad" people!

Human Error	Unintentional	Mistake, Slip or Lapse
At-risk Behavior	Intentional, but...	Deviation - Not aware of risk or belief risk is justified
Reckless Behavior	Intentional	Deliberate disregard for safety

The system within which people work is almost always the most important determinant of poor individual and organizational outcomes.

ALWAYS try to recognize what type of error took place – and why it took place – before prescribing solutions!

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Reasons for Human Error

- Person Approach:** Error = the cause of "bad" things
 - Errors are due to:** forgetfulness, inattention, poor motivation, carelessness, negligence, and recklessness.
 - Remedies:** appeal to people's sense of fear, writing (yet) another procedure, disciplinary measures, threat of litigation, retraining, naming, blaming, and shaming.
- System Approach:** Errors are to be expected, even in the best organizations. Errors are consequences rather than causes, and generally due to "upstream" systemic factors.
 - Ex. recurrent error traps due to organizational processes
 - Countermeasures do not assume we can change the human condition, but rather change the conditions under which humans work.
 - Central idea of system defenses. When an adverse event occurs, the important issue is not who made an error, but how and why the defenses failed.

Reason J. Human error: models and management. BMJ. Mar 18, 2000; 320(7237): 768-770.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1117730/>

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Factors in Adverse Events

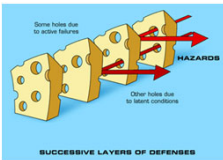
- **Active failures:** unsafe acts committed by people who are in direct contact with a person or system.
 - Ex. slips, lapses, fumbles, mistakes, and procedural violations.
 - Direct and usually short-lived impact on the integrity of the defenses.
 - The **person approach** generally goes no further for the causes of an adverse event once they have identified these proximal unsafe acts.
- **Latent conditions:** inevitable weaknesses within a system.
 - All such strategic decisions have the potential for introducing weaknesses into the system (ex. management, procedures, system design).
 - Result:
 - 1) Error provoking conditions within the local workplace (ex. time pressure, understaffing, inadequate equipment, fatigue, inexperience)
 - 2) Long-lasting holes or weaknesses in the defenses (untrustworthy alarms and indicators, unworkable procedures, design deficiencies, etc.).

Source: J. Reason article

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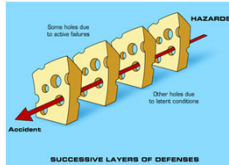
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The Swiss Cheese Model



- Every step in a process has the potential for failure, to varying degrees.
- Holes are opportunities for a process to fail – whether latent conditions, or active errors.
- Each slice is a “defensive layers” in the process that is an opportunity to stop an error.

- A problem may pass through a hole in one layer, but in the next layer the holes should be in different places, and the problem should be caught.
- For a catastrophic error to occur, the holes need to align for each step in the process allowing all defenses to be defeated and resulting in an error.
- The more defenses you put up, the better. Also the fewer the holes and the smaller the holes, the more likely you are to catch/stop errors that may occur.



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Forces driving human error

- **Variability:** Consider specific differences in needs and capabilities that represent variability that could increase the risk of human error and adverse events.
- **Complexity:** What complex processes do your staff have to carry out? How many steps (opportunities for error) are there in these processes?
- Let's put these together – where are there complex tasks that ALSO have variability?
 - Is this due to a lack of standardization? Or necessary variability?
- Are there other factors that resonated with you in your programs – such as coupling, distractions, dependence, time limitations, person-specific characteristics?

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Risk Screening & Addressing Risks of Harm

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How well does your organization currently screen for individual risk?

- How do you currently screen for risks?
 - What information sources do you use?
- Do you frequently have the information you need to do this assessment for people newly entering services?
- How do you separate the essential from the non-essential?
- Is risk screening an annual process?
 - How do you detect emerging risks?

- Are the impacts (type/setting), probability and discoverability considered for the identified risks?

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DBHDS Annual Risk Awareness Tool (RAT)

used by Case Managers for DD Services

Areas covered:

<ul style="list-style-type: none"> • Pressure Injuries • Aspiration Pneumonia • Falls with injuries • Dehydration • Bowel Obstruction 	<ul style="list-style-type: none"> • Sepsis • Seizure • Community Safety Risks • Self-harm • Elopement • Lack of Safety Awareness
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- Incorporate into ISP process
- Use to develop awareness in staff of new or emerging conditions/risks throughout the year

Released June 2020. Developed in conjunction with input both from the regional community nursing meeting groups and from the DD Settlement Agreement's Expert Reviewer 36

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How well are identified risks incorporated into individual plans?

How do you make sure identified risks are recognized in the individual support plan and appropriately addressed?

Do plans identify what is to happen, when it is to happen, how it is to happen (e.g., the use of specific steps in a written program) and who will be responsible for making it happen?

How do you monitor and adjust plans?

Where do you perceive gaps?

How well is this working?

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Risk & Balance

- Risk is all around us
- Risk is not something to be reduced to zero.
- Focus on recognizing the most significant risks: Those that pose the greatest threat to safety and well-being
- Then, set realistic and practical priorities when developing individual support plans

It is essential that the Support Plan

BALANCE

Personal Goals and Preferences

with

Safety and Health

in order to achieve a good Quality of Life and meet CMS requirements.

From the Risk Management in Developmental Disabilities Series
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So, where to begin?

Gather information about risk and personal goals and preferences

1. Ask the person – use structured tools where available
2. With permission, ask others
 - Gather information about factors that might compromise the person's health or safety. Talk with the doctor, nurse, other professionals that are working with the person. Most importantly review issues with the individual's support staff or other primary caregivers.
3. Review the records & any structured Assessments

To help you identify possible concerns that may be placing the individual at risk of poor health or compromised safety.

→ Integrate this information

- Identify areas for needed changes
- Make a plan

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IDENTIFYING Special Concerns and Risks to Health and Safety

RISK FACTORS that should be reviewed:

- UNUSUAL INCIDENTS
- HEALTH Risks
- FUNCTIONAL Risks
- BEHAVIORAL Risks
- HOME & ENVIRONMENTAL Concerns

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IF SIGNIFICANT RISKS EXIST ADDRESS THEM IN THE PLAN

REMEMBER to evaluate whether or not the person will need any changes to his/her services, level or type of support and adjust the plan accordingly. Look at possible changes to:

- Intensive Staffing/Supervision
- Written Guidelines
- Self/Staff Training
- Periodic Monitoring
- Professional Assessments
- Nursing Care Plan
- Clinical Services
- Home or vehicle adaptation
- Emergency Staff Backup Plan
- Appointment of Guardian
- Investigation or Referral to other Agency for Review

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Consider the following scenario:

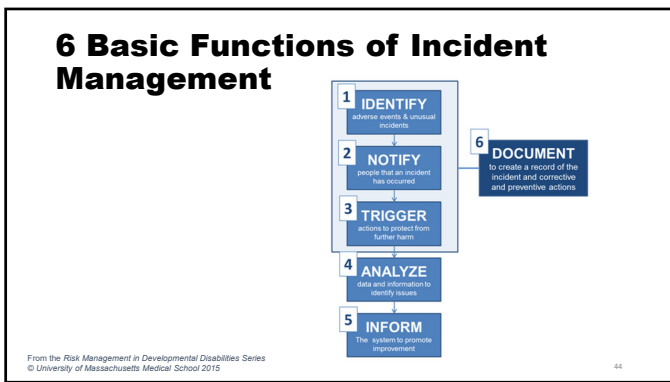
- While reviewing recent incident reports, you notice that Thomas has fallen three times in his home. The same staff person has filled out the accident reports because all three accidents occur on his evening shift just around the time Thomas is getting ready for bed. You initiate an investigation and reassign the staff person temporarily in case there is any evidence of abuse and neglect.
- Let's consider this response...

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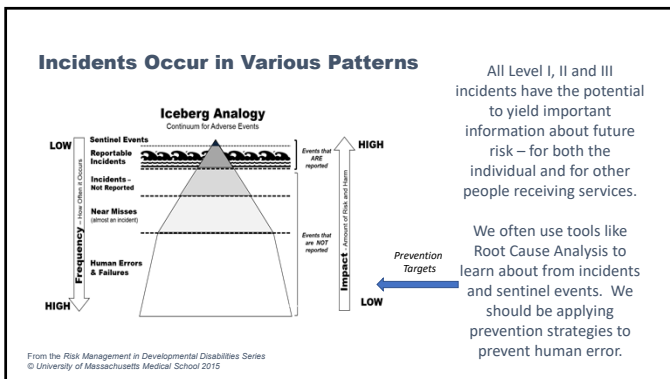
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Incident Management & Risk Triggers

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Serious Incident Management Policies

12VAC35-105-160.J - The provider shall develop and implement a serious incident management policy, which shall be consistent with this section and which shall describe the processes by which the provider will document, analyze, and report to the department information related to serious incidents.

How will the provider:

- o Collect, maintain and review all serious incidents including Level I serious incidents at least quarterly
- o Document persons identified by individuals to receive notification of serious incidents and ensure that individual's authorized representatives and anyone else identified by the individual receives notification of serious incidents within 24 hours; and
- o Ensure that Level II and Level III serious incidents are reported to the department within required timeframes

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Aspects of Effective Incident Management Policies

- Establish, at a minimum, expectations regarding:
 - **Who** is included in the covered population for reporting incidents and who are mandated reporters
 - **What** incidents must be reported and what type of information is required and what are the potential consequences for non-adherence to policy mandates
 - **How** are incidents to be reported, i.e., what method(s) are to be used, what are the timelines for reporting and responding, who must be notified, and what are the documentation requirements
 - **Why** or what is the purpose and aim of incident reporting and management, what are the expectations and requirements for how information regarding incidents are to be used
 - **Quality Improvement** expectations and any requirements for establishing risk reduction and safety enhancement goals and objectives

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Incident Management & Response

- Ensure effective pathways for notification
- A good incident reporting and management system should be able to signal the need for action and/or special review based on the type and severity of an incident.
 - What warrants an immediate response?
 - When is a clinical review needed?
 - When is a behavioral review?
 - When are incidents reviewed for needed changes in service plans?

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Reviewing Incidents

- Incidents that rise to the level of “reportable” are usually very serious (less significant adverse events and “near misses” are easily overlooked and not reported). Level I serious incidents, while not reported in CHRIS, should be reviewed quarterly per regulation.
- They are relatively strong predictors of future risk of harm.
- A less visible (not-reported) incident can also provide useful information about emerging risks: risks that will most likely contribute to an adverse event sooner or later. **Do not ignore these.**
- Pay special attention to repeat incidents
 - the presence of an increase in reported incidents can indicate that individuals may be undergoing major changes in their life (e.g., family, work, social) that may need to be quickly addressed.

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Incident Reports

- **A PATTERN OF UNUSUAL INCIDENTS MAY MEAN THE PERSON'S NEEDS ARE NOT BEING PROPERLY ADDRESSED** leading to risks and special concerns that can result in significant deterioration of the person's quality of life and possible harm.
- Examples:
 - Emergency Hospitalization
 - Neglect or Abuse Report
 - Missing Person Report
 - Fire resulting in injury or hospitalization
 - Police Arrest
 - Victim of Aggravated Assault or Rape
 - Unusual incident or behavior not normally exhibited that was dangerous, illegal or life threatening
 - Eviction resulting in a period of homelessness
- Incidents reports offer important information about potential emerging risks, as well as systemic weaknesses that permit human error to result in, or almost result in harm (near misses).

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A FEW QUESTIONS TO CONSIDER

RE: UNUSUAL INCIDENTS

- Are there any **injuries** that have required emergency care? If yes, what **type of injury** and what was the **cause**? Will it require an adjustment to the level of support the person needs? Will they require a new place to live or work?
- Is there a **new medical condition** that has resulted in the need for sudden unplanned hospital care? If yes, what is it and will it require new or different supports?
- Did a **behavioral crisis** lead to the need for emergency or police involvement? If yes, is the current **medication** and **behavioral support** plan adequate? Will it require an adjustment to the level of support the person needs?
- Has there been any substantiated **abuse**? Who is the perpetrator? Is the person adequately protected?
- Are **support staff** properly trained and capable of providing the needed support? If no, how will this be addressed?

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Incident Management - Analysis

- Information and data pertaining to unusual incidents need to be well organized and properly analyzed in order for it to become a useful risk management and quality improvement tool. This aspect of the system's evaluation focuses on determining the extent to which your system promotes the appropriate use of statistical analyses, including:
 - Descriptive analyses to show
 - differences between types and levels of incidents (over time and/or across groups, programs, etc.)
 - trends over time (across groups, programs, regions, etc.)
 - differences between service types (across groups, programs, providers, regions, etc.) and between areas, districts or regions
 - Analysis of the types of incidents by service recipient, service setting or program, and by geographic area or service line
 - Risk adjustment and conversion of incident data into rates (number/population)
- What types of reports are you using for incident data?

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Example: Hospice Use by Individuals

- **Issue: Informal (small) trend:** Incident Review Committee concerned people with terminal conditions were not benefiting from a good death.
 - Data collected for decedents: 29% utilized hospice services; lower than state rate for general population
- **Why?** Interviews with staff, agencies and hospice providers yielded information about gaps in planning, gaps in knowledge and policy barriers.
- **Actions:** Increased awareness of hospice and end of life planning by:
 - Data collection: Amended mortality form and health care record
 - Education/discussions with service and hospice providers
 - Policy change to address identified barriers to hospice
- **Impact:** Increased use of hospice by 10% within 3 years
- Continue to monitor and collect data re: use of hospice

We measured & benchmarked!

Then we asked WHY??

And then we measured again!

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Risk Trigger: What are Triggers?

- A set of **standards** or criteria that indicate an individual or service location may be at **heightened risk** of future harm
- **"Red Flag"** indicating a person or program has met a certain **threshold** of incidents
 - Triggers make sure those responsible for planning and provision of supports are **alerted** to the potential for risk of harm
- Reduces likelihood issues will fall through the cracks
- The pattern of incidents **Triggers the need for a review**
 - Assures that a more complete analysis is conducted - if warranted
 - Reviews are individualized
 - Response is to be based on the facts of the situation
 - Does **NOT** automatically mean a risk plan is needed
- **NOT** to supplant basic service planning, clinical review, or other oversight and monitoring activities



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Triggers & Thresholds

- **Trigger** means a single predefined event or change in status, which indicates that an actual or potential risk has occurred or is about to occur. Triggers are events of significant risk and they signal the need for immediate review and actions to reduce the risk and prevent harm.
- **Threshold** means that a series of predefined events or changes in status have occurred, which indicate that a level of unacceptable risk has been reached. When a risk Threshold is reached, it signals the need for review and actions to mitigate risk and prevent harm.

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DBHDS Individual Care Concern Thresholds

- **Serious Incidents:** Three or more unplanned medical hospitalizations, emergency room (ER) visits or psychiatric hospitalizations within 90 days for any reason.
- **Multiple (2 or more) unplanned medical hospitalizations or ER visits for the same condition or reason that occur within 30 days.**
- **Any combination of 3 or more incidents of any type within 30 days.**
- **Multiple (2 or more) unplanned hospital admissions or ER visits for any combination of the following serious incidents: falls, choking, urinary tract infection, aspiration pneumonia, or dehydration within 90 days.**
- **Any incidents of medically verified decubitus ulcers or bowel obstruction.**

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Providers can develop their own triggers

- Identify Areas of Greatest Risk,
- Assess Each Risk
- Test Your Triggers and Thresholds
- The threshold may be established for . . .
 - A single individual (minor fall pattern)
 - For a program (overtime worked, med admin errors)
 - For certain types of incidents (ER use for UTI)

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Root Cause Analysis & Contributory Factor Analysis

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Structured Analysis

- The key to solving a problem is to first truly understand it. Often, our focus shifts too quickly from the problem to the solution, and we try to solve a problem before comprehending its root cause. What we think is the cause, however, is sometimes just another symptom.
Institute for Healthcare Improvement, Boston, Massachusetts, USA
- Root Cause Analysis & Contributory Factor Analysis are both types of Structured Problem Analysis
 - There is a range of 'depth' in these analyses, but both use the same principles. Contributory Factor Analysis is a more basic process, with Root Cause Analysis generally referring to a more in-depth analysis.

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Structured Analysis

- In incident reviews, when teams observe multiple incidents due to similar preventable causes, or that have similar aspects in terms of the chain of events or identified failures, the situation is ripe for structured problem analysis to get to the root cause
- Without using a structured process to do this, it is easy to miss what's really driving the issues.
- Frequently, we stop at more proximal causes because they're closer to the problem we can see.
- Yet, our efforts to address these proximal causes are often not sufficient to address the issue because we're not focused on the root causes in our systems.
 - As a result the same problems continue to occur

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DBHDS Regulations - RCAs

- Root cause analysis (RCA), as defined by 12VAC35-105-20, is "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."
- **Frequency:** 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 a service or on the provider's premises.
- **Content:** For any reported incident the RCA should include a) a detailed description of what happened; b) an analysis of why it happened, including an identification of the underlying causes of the incident identifiable underlying causes of the incident that were under the control of the provider; and c) identified solutions to mitigate is reoccurrence and future risk of harm.

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DBHDS Regulations (continued)

More detailed RCA's:

- **RCA policy:** The provider shall develop and implement a root cause analysis policy for determining when a more detailed RCA, including convening a team, collecting and analyzing data, mapping processes, and charting causal factors, should be conducted.
- At a minimum, the policy shall require for the provider to conduct a more detailed RCA when:
 - 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;
 - 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;
 - 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
 - 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.

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WHAT IS ROOT CAUSE ANALYSIS?

Root Cause Analysis is an analytic tool for evaluating adverse events that have already happened in order to identify:

- **WHY** they happened
- **What** can be done to **PREVENT** them from happening again

Focus is on understanding factors that contribute to and cause adverse events and then designing targeted prevention strategies

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Discover WHY!

Root Cause Analysis is a formal **process of discovery** that works to identify **all** of the **human and system factors** that contributed to – or allowed – an adverse event to happen.

```

    graph LR
      subgraph CF [Contributory Factors]
        HF[Human Factors]
        OF[Organizational Factors]
        TF[Technical Factors]
      end
      CF --> EF[ERROR or Failure]
      EF --> AE[Adverse Event]
  
```

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SOME BASIC TENETS OF RCA

- The goal of RCA is **PREVENTION**
- **Belief** = errors and failures result from **flaws in the system** – not just people’s actions or inactions.
- Try to find out **WHY** someone made a mistake, not just who made it – or what mistake was made.
- RCA requires thorough analysis of
 - Human factors
 - Organizational support systems
 - Formal **and** informal processes
- Based on a series of “**WHY?**” questions to identify actual and potential **Contributory Factors** that led to and set the stage for the adverse event.

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INVESTIGATION v RCA

<h3>INVESTIGATION</h3> <p>PURPOSE: Identify WHAT happened & WHO was responsible</p> <p>TYPICAL QUESTIONS:</p> <ul style="list-style-type: none"> • What exactly happened, where and when? • Who was responsible? • Did they follow procedure? • Did they violate any laws, regulations or policies? • What disciplinary or enforcement action may be needed? • Is the person safe now? <p>FOCUS: is often on INDIVIDUAL fault</p>	<h3>RCA</h3> <p>PURPOSE: Identify WHY it happened & HOW to prevent its reoccurrence</p> <p>TYPICAL QUESTIONS:</p> <ul style="list-style-type: none"> • What factors (especially organizational) may have contributed to human error? • Are others at similar risk? • What could have prevented it? • What changes to our systems and processes should we make? • What took place before and led up to the incident? <p>FOCUS: is on SYSTEMS change</p>
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Identify Factors that may have caused the Incident

After careful review of the incident and relevant documentation, begin the process of analysis to discover not only what happened, but **WHY it happened**. This leads to a better understanding of what factors allowed or contributed to any error.

- Review the **INCIDENT** – provide background information
 - Use contextual knowledge too – QI & program staff have valuable info
- Review **SEQUENCE of events** for the actual incident
- Compare to **WHAT SHOULD HAVE HAPPENED**
 - Identify deviations and system errors/failures
- Identify the **PROXIMATE CAUSE** – what was or was not done immediately before the incident that resulted in the event.

REMEMBER: Focus is **NOT** on **BLAMING A PERSON** or group! It is on **FACTORS** that did/could have led to identified errors.

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What is Contributory Factor Analysis?

- Grounded in Root Cause Analysis process
- A “lighter” version that focuses on identifying systems factors that contribute to an incident but with lower resource use than a full RCA
- Should be conducted with a team that understands the local context and environment where the service is provided, and the circumstances of the event being reviewed.

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Drill down deeper



- Keep asking **“WHY”**
 - “Why were staff afraid to call the nurse?”
 - “Why wasn’t there demonstration of competency?”
 - “Why was the procedure so confusing?”
 - “Why didn’t he check the person on time?”
 - “Why was she not aware of the signs of illness?”
- Contributory Factors are often related to a system or process problem
- Should **not** be focused on an act of omission or commission by a person – but rather what was present or absent that allowed the human error or equipment failure to occur

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When reviewing incidents - consider the System's Role

- How did various components of your system set people up to succeed or fail?
 - Tools people use (protocols, policies, procedures and the materials and equipment that are provided by the organization)
 - Tasks and activities they engage in (that are scheduled, dictated and regulated by the organization)
 - Competing priorities or other stressors
 - Organizational culture, expectations, messaging from leadership

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4 Major Questions

to be considered in an Incident Review

- **Opportunity to RECOGNIZE:** evidence that a medical, health, behavioral, environmental or other physical or social risk contributed to an incident and was not identified in time to take preventive action?
- **Opportunity to PLAN:** evidence that a medical/health, behavioral or other physical or social risk contributed to the incident and was identified but not properly addressed in the person's plan of care and support?
- **Opportunity to ACT:** evidence that an intervention or support action prior to the incident did not occur that could have prevented the incident?
- **Opportunity to COMMUNICATE:** evidence that inadequate communication contributed to the incident. *(And, if it did, was it the Person or family to staff, staff to staff, clinician to clinician, etc., or was it related to inadequate documentation, issues of supervision, problems with management or organizational leadership, etc.?)*

*Adapted from "Mortality Review and Reporting" by S.D. Staugaits and E. Lauer - one of seven on-line courses under development by UMMS and Praxis, Inc. and funded by an NIH grant #42HD063379-02. Risk Management in DO.

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Use Guiding Questions for a High Quality Review

- Ask the 4 questions regarding failures to Recognize, Plan, Act and Communicate
- Consider where there are factors likely to affect other people receiving services
 - THESE are important to emphasize in your review
- Then, consider the **5 Whys** (or similar tool) about these factors to understand systemic/root causes
- **Example Prompting questions:**
 - Were there failures of an existing requirement (e.g., policy or practice standard) or a lack of a requirement that contributed to this death?
 - Were personnel adequately trained and supervised? Did they possess the necessary skills...?
 - What organizational issues may have contributed to the identified failure? [from Staugaits and Lauer, pp. 68-9.]

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Fishbone Analysis

- 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.
- Complete this diagram in an interdisciplinary committee including people who are knowledgeable of the processes and systems involved in the problem or event to be investigated.

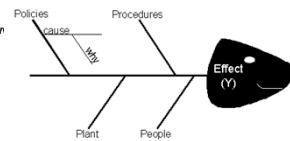
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Cause-and-Effect (Fishbone) Analysis

- The “problem” or “effect” is at the mouth of the “fish.” Be as clear and specific as you can about the problem.
 - Beware of defining the problem in terms of a solution (e.g., we need more of something).
- It’s often helpful to ask a why question here.
 - Failure to recognize: *Why was this person’s medical condition identified so late?*
 - Failure to plan: *Why was this person’s service plan not changed to reflect their changing support needs?*
 - Failure to act: *Why was the protocol to manage this person’s medical condition not followed?*
 - Failure to communicate: *Why was did the staff not report the person’s symptoms to their supervisor or call the doctor?*



<https://www.isixsigma.com/tools-templates/cause-effect/cause-and-effect-aka-fishbone-diagram/>

Adapted from ADP Resource

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Completing the analysis

- The “bones” of the fish are the contributing factors that caused the problem. They are organized by categories.
 - Major categories often include: equipment or supply factors, environmental factors, rules/policy/procedure factors, and people/staff factors.
- Brainstorm all the possible causes of the problem.
 - This is a helpful area to use the 5 Why’s.
 - Write each causal factor as a branch from the appropriate category (places it on the fishbone diagram). Causes can be written in several places if they relate to several categories.
 - Again asks “Why does this happen?” about each cause. Write sub-causes branching off the cause branches.
 - Continues to ask “Why?” and generate deeper levels of causes and continue organizing them under related causes or categories. This will help you to identify and then address root causes to prevent future problems.

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Picking an Analysis Strategy

The Five Why's

- Simple to use and understand
- Can be used in any meeting format
- Best for cases with a single pathway from Root Cause to adverse event

Fishbone Diagram

- Visual mapping can add clarity to connections between contributing factors and event
- More complex to do in real-time and requires visual sharing during meeting
- Can handle multiple causal pathways in a clear fashion

It's also ok to use both – or start with one and move to another as you explore the case!

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Case Scenario #1

- Incident: Allegation of Neglect- Medication error
- Person did not receive morning medication for 3 out of 5 days in a week
- Involved 2 staff who made administration errors

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What do we know about the program?

- Four people living in a community home
- Two DSPs on during morning shift
- Both staff up-to-date on training on medication administration
- The regular staff were on shift that week.
- Staff had been with organization for >1 year.

What else do we know?

- Person received new medication at the beginning of the week
- Prescription written for med to be given at 8:00 AM
- Transportation for day programming picks up people at 7:50am (2) and 8:10 am (2)

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Data Measurement & Analysis

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Data Tools & Processes

Where does your data come from? How is it collected?

Examples of Custom Data Tools & Processes

- Regular monitoring of reports
 - rates and internal benchmarks that adjust over time
- In-depth post-incident screening tools
 - aid in gathering evidence to plan interventions
- Consulting to design cross-disciplinary systemic risk review groups
 - monitor and address emerging risk concerns
- Look at the big picture:
 - How are your current tools working? What modifications are needed?
 - If you select new tools – how do they integrate with existing tools?

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Data Tools across System Levels

LEVEL	FOCUS	TOOLS
Individual	Identify Plan Prevent	Risk Screening Triggers & Red Flags Specialized Evaluations Person-Centered Planning Emergency Preparedness Plan
Program	Monitor Correct/Remediate Prevent Improve	Incident Reporting/Triggers & Red Flags Case Management & Monitoring Medication Occurrence Reporting Investigations Licensing & Certification Review Inspection/Survey/Audit Complaint Reporting
Organization	Analyze Improve	Mortality Review & Analysis Data Analysis & Benchmarking Root Cause Analysis FMEA Goal Setting Public Reporting

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Approach

- Data-driven approach to identifying systemic weaknesses and developing targeted solutions
 - Define
 - Measure
 - Analyze
 - Design
 - Verify
- Strategic application of statistical analyses to understand variation – natural fluctuation or ‘real’ differences
- It is best practice to use the data you collect to identify risk patterns and trends
 - Consider: What other information do you gather? Do you use it effectively?
 - Are you collecting the right information to inform the questions you need to answer?

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How good is your data?

Good information systems will help ensure that:

- Data is collected the same way - each time - by all persons who input the information (i.e., the data is **reliable**).
- What is collected is accurate and unbiased information (i.e., it is **valid**).
- The type and amount of information that is reported is complete and sufficient to accurately answer intended questions (i.e., it is **comprehensive**), and
- The data and associated information is collected and reported within prescribed timelines (i.e., it is **timely**).

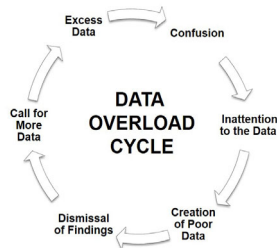
How often do you evaluate your data?

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Beware!



From the Risk Management in Developmental Disabilities Series
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Data Analysis Plan

- In order to work through questions and solutions it is helpful to create an analysis plan. Such a plan should list:
 - desired questions the analysis must answer,
 - considerations about the data quality (reliability/validity/completeness),
 - the amount of resources and effort that may be required in gathering and "cleaning" the data that will be used in the analysis, and
 - the relative priority of the questions to be answered by the analysis (i.e., what are the most important questions and issues that need to be addressed versus what might be "nice" to know, but is not really essential).

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Tips – using data for systemic improvement

- Triangulate when possible
- Use benchmarks, select carefully
- When is a difference really a difference?
 - *Application of statistical testing*
- If you can't measure everything, consider the use of valid samples to inform your question
- When designing new data collection tools/systems, "reverse engineer" from the reports you seek backwards to design collection tools
- Consider a range of audiences in how "data" is presented to ensure it's understood and useful
- Be sure to engage discussion, don't just show/tell

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Capturing impacts

- Understand the baseline
- Make an effort to understand and capture where you're starting
 - Important to document things 'as they are' at the start of efforts
 - Consider all possible domains that could be impacted, try to characterize or quantify current state
- Ensure impact is captured
- Keep a timeline of activities (inputs & outputs)
- Conduct ongoing measurement of outcomes

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Importance of Benchmarks

- Appropriate, objective benchmarks can be valuable for understanding strengths and weaknesses within a service system to better enable the system to establish focused targets for quality improvement.
- Benchmarking must be done with extreme caution to ensure that the comparison data is valid. If comparison groups are not selected appropriately, or are not properly risk adjusted, one can end up with faulty and extremely inaccurate conclusions.
- Internal Benchmarks – data over time, goals
- External Benchmarks - Outcomes in other groups, External public health targets

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Steps for using benchmarks

1. **Understand the data.** Ensure it is accurate, valid, reliable and useful.
2. **Understand the source of the benchmark.** Understand how the information was collected. Evaluate differences
3. **Evaluate the relevancy of the data.** Understand how and why goals was established, and whether it fits your data.
4. **Compare the organization's data to the benchmark.** Take special care to ensure that all the data being reviewed is aligned as closely as possible to the benchmark.
5. **Plan next steps.** Review whether the comparison data provides sufficient information to answer the target question. Where possible, use multiple measures to develop a complete understanding of the results of an analysis.

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Annual Systemic Risk Assessment

According to DBHDS regulations: providers shall conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address at least the following:

1. The environment of care;
 2. Clinical assessment or reassessment processes;
 3. Staff competence and adequacy of staffing;
 4. Use of high risk procedures, including seclusion and restraint; and
 5. A review of serious incidents.
- This assessment process should integrate a variety of information sources to reflect on the identified areas.
 - Consider: Are you collecting the right data to inform these areas? How are you integrating the data and using it to identify areas for improvement? Are you measuring whether your strategies result in improvement?
 - **A Proactive Approach:** assessment of an organization's risk screening and incident management systems to prompt specific areas of consideration for agencies to use as a guide
 - **Apply systemic learning:** reflect on what you've learned from RCAs and reviews of patterns and trends in incidents to understand where quality improvements is needed.

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Developing systemic preventive strategies & corrective actions

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Designing Preventive Strategies

- How do we get from contributing factors and root causes to preventive strategies?
 - Think about why someone did or didn't do something, what might need to be changed or adapted to prevent a slip, mistake, unsafe practice or other type of error. Consider the **7 Common Reasons for staff error**
 - The more specific your contributing factors and root causes are, the easier this will be to identify.
 - Discuss potential barriers that could automatically or physically interfere with or obstruct the error from taking place. **Brainstorm!**
 - Seek Information from Outside your Organization. **Find out what has worked elsewhere!**
- "A systems thinker is a perpetually curious person who never thinks they have the whole answer but is always willing to know what the next step to take is" – Don Berwick, MD, founder of the Institute for Healthcare Improvement
 - Focus on taking the next step, rather than immediately solving the entire problem

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Avoiding corrective action traps

Frequently, the response to an adverse or serious incident is to

- a. Discipline or fire the staff involved, and/or
- b. Retrain the staff

Let's consider what this may actually accomplish:

- We fire the staff to show we've done something about the incident.
 - But, did our system set that staff up to fail such as to make a forced error, or choose between two bad options? If another staff person was in the same situation would they make the same decision/conduct the same action?
 - If so – we have a systems issue not a person issue. And we just lost staff without fixing the problem.
- And we retrain everyone. But, is that the right solution?
 - But what if the training is adequate for the situation the staff face?
 - What if the training doesn't translate into skill when the staff need it?
 - Do we need job aids or other tools to help guide staff?
 - Then, we've just wasted valuable resources' retraining' – a strategy that may not have been effective the first time, and may change anything going forward.

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Types of Prevention Strategies

Primary: prevent a condition/ event leading to morbidity/ mortality from occurring through education and services.

- Strategies to reduce falls (removing area rugs, rearrange furniture to create clear path)
- Integrated programs to support healthy lifestyles and weight management (e.g., exercise and nutrition)

Secondary: detect/treat conditions/injuries early in order to minimize effects and prevent further morbidity/mortality.

- Training for direct-support staff about recognizing important signs and symptoms of illness or serious medication side effects
- Programs to advocate for and support people to receive preventive cancer screenings (mammography, colonoscopy/sigmoidoscopy)

Tertiary: treat/manage conditions/injuries optimally based on practice standards and evidence in order to reduce fatality rates.

- Diabetes management education
- Aspiration management protocols and education to support staff to prevent acute aspiration or aspiration pneumonia

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Ask...

- Was there a failure to do something? Why did that happen?
- Can we go beyond blaming an individual? (A: Very often, YES, there are systems failures as well!)
- Are we seeing something that could happen other places, and should something be addressed across the organization, or subgroup (e.g. region)?
- Be judicious about recommending a brand new monitoring process, checklist, etc. First consider whether an existing service aspect can be modified, or maybe replaced by a better one?
 - *Can you tie in existing monitoring systems? Provide them with better information to do their job, etc.?*
- Is there something that we are assuming was not done? Should we ask for more information, or encourage the agency to review their own practices to ensure necessary steps occurred?

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What are the critical opportunities for improvement?

- When an error is identified, consider **why** it occurred. Think beyond an individual making a poor decision, action or inaction. What led them to this?
 - If this set off a chain of events, consider what enabled (or did not prohibit) the evolution of events?
- Could this event happen to another person? Is it likely to happen again?
- Are there recommendations at a systems level (such as adapting policy, procedure, routine, specific training) that could help avoid this in the future?

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When Formulating Recommendations

<p style="text-align: center;">DO</p> <ul style="list-style-type: none"> • Develop recommendations that tie to 'opportunity to RECOGNIZE, PLAN, ACT, COMMUNICATE'. • Identify and refer any pressing safety issues to appropriate group. • Review investigation report and summary with a 'culture of safety' approach: ask <u>why</u> did failures happen? • Making note what worked well – and how those strategies can that be expanded 	<p style="text-align: center;">DON'T</p> <ul style="list-style-type: none"> • Provide recommendations that do not directly tie to a systemic issue • Provide recommendations that do not have the potential to improve services in the future • Repeat recommendations from investigations • Assume the local staff did not do something. Ask a question instead. • Solely emphasize blame or fault with the local staff
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Examples of recommendations

Area of Opportunity	Sample Key Finding	Sample Recommendation
Recognize	Evidence that staff were not adequately trained	'Consider implementing training for [Staff] on [Topic] for individuals at risk of [condition]'
	Evidence of lack of monitoring/supervision	'Ensure adequate staffing levels when [root cause of staffing gap]'
Plan	Policies were not in place to address an minimize risk	'Ensure that policies for [event] exist and that their implementation is routinely monitored'
Act	Evidence that staff did not act in a timely fashion	'Review policies and processes to ensure that staff are empowered to act in timely fashion if [event] occurs'
Communicate	Evidence that documentation was not adequate	'Ensure system of documentation of [risk area e.g. Pica] adequately informs staff and supervisors of risk and actions to take to reduce risk'

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Avoid....

- Vagueness
 - E.g. "Establish documentation protocols and retrain staff while spot checking documentation"
- Clinical advice as if the person was still alive:
 - E.g. "Do not assume comfort but actually check for responsiveness. Fluctuating vital signs should be a clue for further evaluation, not just to monitor; especially since this individual had a PEG and other intestinal compromises."
- Assuming no system is in place:
 - E.g. "Establish protocol for missing individuals and review annually"
- Second-guessing individual clinical decisions

These are not likely to yield actions on which the organization can act. Refer serious concerns to appropriate staff within the organization.

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Good recommendations

- Revise training opportunities on calling 911
 - Include scenario-based drill to ensure staff can apply strategies in stressful situation
- “Ensure adequate coordination system in place to accurately schedule and follow up on medical appointments when ordered”
 - Does not assume systems is not in place
 - Notes specific areas for systemic improvement to improve quality for other people being served
- “Review with staff the importance of noting and reporting changes in behaviors to supervisors to help reduce untoward events.”

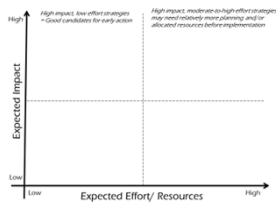
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PRIORITIZE SOLUTIONS

- 3 Major Criteria:
 - **Effectiveness**
 - **Feasibility**
 - **Resource Requirements**
- Consider Agency “Readiness” for Change
- Use Efficiency Diagram to illustrate priorities



BE PRACTICAL!

Cost! Time and Effort! Other agency Priorities! Resources!
All need to be taken into consideration.

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Risk Management in Developmental Disabilities

Virginia’s licensed developmental disability providers are required to implement risk management processes. Through CDDER/ University of Massachusetts Medical School, DBHDS offers courses on the development and implementation of risk management processes that meet Virginia’s requirements to identify and mitigate risk, while establishing a culture of continuous quality improvement.

- **Risk Screening in Developmental Disabilities**
 - Learn how to recognize and plan for the mitigation of health and safety risks for people with disabilities.
- **Incident Management in Developmental Disabilities**
 - Learn how to build a system to identify, notify, trigger, analyze, inform and document incidents. A good system will promote and direct safety and quality improvement.
- **Root Cause Analysis in Developmental Disabilities**
 - A structured approach and process guide to analyze significant adverse events to understand why the events occurred and how to prevent events going forward.
- **Data Analysis for Quality Improvement**
 - Objective measurement and analysis is a powerful management tool, learn how to use data effectively, understanding the benefits and limitations of incident data.
- Each course contains access to the Core Modules
 - Getting Started: Risk Management in Developmental Disabilities
 - System Design in Developmental Disabilities

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Course Access

- One individual license per course for each DBHDS **Developmental Disability provider agency** will be available free of cost. Agencies can have different staff use the individual license across courses.
 - **Information and Registration for no-cost license:** <https://bit.ly/3ij8nTH>
- Certificates of completion are available to users who complete the course and pass the knowledge check at the end of the course.
- Agencies may also purchase more licenses for course access, and access low-cost workbooks with the course content here: <https://shriver.umassmed.edu/cdder/rmdd>

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Questions?

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