

UNDERSTANDING THE PROBLEM (Steps 1 & 2)

Tool	Purpose	Strengths / Advantages	Weaknesses / Difficulties
Flowchart (process map)	Understand the flow of activities in a process and interrelationships between processes	<ul style="list-style-type: none"> Focuses on linkages and hand-offs between functions, job titles, etc. Uses graphics 	<ul style="list-style-type: none"> Difficult to decide on the level of detail Do not have the level of detail found in procedures May be of limited value if a process is seriously out of control
Direct observation	Determines the current level of compliance with requirements as process steps are completed	<ul style="list-style-type: none"> Helps with understanding the process and work flow Provides additional information not included in the NCE report 	<ul style="list-style-type: none"> Can be intimidating and confused with blame
Document review	Understand the requirements of the process	<ul style="list-style-type: none"> Explains how things are supposed to happen Describes the requirements and expectations of the organization 	<ul style="list-style-type: none"> May not be adequate or correct May not exist May not be easy to understand
Record review	Verify the outputs of defined criteria	<ul style="list-style-type: none"> Provides verification of completed tasks Provides objective evidence when requirements are unfulfilled 	<ul style="list-style-type: none"> May not be accessible May not be complete or provide sufficient detail
Interview	Providing a forum for process owners to describe documented and undocumented practices and to provide details of what happened	<ul style="list-style-type: none"> Helps with understanding the process and work flow Provides additional information not included in the NCE report May be the only source of information about a process 	<ul style="list-style-type: none"> Relies on people's time and availability Often subjective Can be intimidating and confused with blame
Photographs	Captures a visual snapshot of the problem	<ul style="list-style-type: none"> Communicates complex information at a glance 	<ul style="list-style-type: none"> May need permission Depending on the context, may be difficult to note the scale Viewpoint may change depending on angle or perspective
Pictogram	Creates a visual that allows representing the spatial orientation of a problem's symptoms (e.g. floor plan, picture of a body to locate injuries)	<ul style="list-style-type: none"> Emphasizes the spatial factor 	<ul style="list-style-type: none"> May not be applicable to the problem

IDENTIFY THE POSSIBLE CAUSE (Step 3)

Tool	Purpose	Strengths / Advantages	Weaknesses / Difficulties
Brainstorming	Generate as many ideas as possible in a creative exercise	<ul style="list-style-type: none"> Uncovers causes that would otherwise be ignored or missed Involves many people 	<ul style="list-style-type: none"> One or few people can dominate No anonymity is possible Undervalued because it is fun
Brainwriting	Generate as many ideas as possible	<ul style="list-style-type: none"> Involves many people Enables anonymity 	<ul style="list-style-type: none"> Can be less spontaneous than brainstorming
Process Step Variation	Brainstorm variations that may occur at each step of the failed process that caused the problem	<ul style="list-style-type: none"> Focuses on the failed process involved with the NCE 	<ul style="list-style-type: none"> The scope of the problem may be poorly defined The boundaries of the process may be poorly defined
Logic tree analysis (WHY – WHY diagrams; abbreviated fault tree analysis)	Graphically display branches of cause-and-effect relationships	<ul style="list-style-type: none"> Creates insight into how causes interact Easy to use 5 WHYS to dig deeper in a branch 	<ul style="list-style-type: none"> If numerous causes occur on many levels, the diagram may be difficult to construct and read
Cause-and-effect diagram (Fishbone, Ishikawa Diagram)	Generate and group problem causes	<ul style="list-style-type: none"> Promotes structure and creativity 	<ul style="list-style-type: none"> Requires more training than other tools to be useful
5 WHYS	Identify chains of cause-and-effect by tracing back the sequence of events that led to the NCE	<ul style="list-style-type: none"> Finds the root cause Uncovers causes that would otherwise be ignored or missed 	<ul style="list-style-type: none"> Requires some creativity and deep knowledge of the problem Of limited value if there are multiple causes contributing to the problem
Is-Is not Matrix	Generate ideas about the problem, focusing especially on what does and does not characterize it	<ul style="list-style-type: none"> Separates clearly between effects that do and don't occur Allows to see contrasts and odd issues more clearly 	<ul style="list-style-type: none"> Can be difficult to generate <i>is not</i> elements

COLLECT AND ANALYZE EVIDENCE TO CONFIRM OR DENY EACH CAUSE (Step 4)

Tool	Purpose	Strengths / Advantages	Weaknesses / Difficulties
Sampling	Gain a representative from a large population	<ul style="list-style-type: none"> Minimizes the data collection effort 	<ul style="list-style-type: none"> Difficult to decide on the type of sampling and sample size The samples chosen may not be representative
Surveys	Collect data from respondents	<ul style="list-style-type: none"> Allows collection of large amounts of data 	<ul style="list-style-type: none"> Good surveys are difficult to design Often low response rate
Tally sheet	Register data in a systematic way	<ul style="list-style-type: none"> Easy to use Ensures that all data are captured 	<ul style="list-style-type: none"> Data categories not specified may be overlooked
Histogram	Portray data graphically	<ul style="list-style-type: none"> Easy to see patterns Uses graphics 	<ul style="list-style-type: none"> Difficult to determine data categories
Pareto chart	Graphically depicts the quantification of problems and their causes (i.e. the few elements causing the most effects)	<ul style="list-style-type: none"> Helps to identify significant causes to known problems or NCEs 	<ul style="list-style-type: none"> Multiple axes in same chart
Scatter Plot (Comparison chart)	Find relationships between 2 variable like outcome improvement and effective solution implementation	<ul style="list-style-type: none"> Easy to comprehend graphics 	<ul style="list-style-type: none"> Difficult to select the independent and dependent variable

Flowchart – Refer to the job aid entitled, *Diagramming Processes*.

Direct Observations – Process observations should be planned for by studying the related standards and requirements. Look for near misses during the observation as an indicator that the process almost failed but the individual caught and corrected it in time while being observed.

Document Review - If the documents are not correct, the system will always have problems. Document issues go beyond correctness. Access, distribution, adequacy, timely removal of obsolete copies are all document issues.

Records Review- Because records document activities or results of activities, look for evidence of what occurred. Knowing specifically what you are looking for in advance will save time during the records review. When reviewing records for causes, know what causes are being evaluated and how they would show-up in the records. A tally sheet may be helpful during the review.

The Steps in Interviewing

I. Prepare for the interview

- Review any data previously collected
- Write questions down to keep the interview of track and are sensitively worded and nonthreatening
- Determine how you will record notes
- Plan on talking only 15-20% and listening 80-85%
- Plan to answer common interviewee's questions
 - Why do you want to talk to me?
 - What will you do with what I tell you?
 - Will my name be used?
 - How long with this interview take?
- Determine location for privacy and lack of interruptions
- Interview one person at a time.

II. Open the interview

- Greet the interviewee
- State the purpose of the interview
- Answer interviewee's questions (See Step I)
- Consider requesting the interviewee to write-down what they remember about the situation before asking any of your questions. This allows a more free flow of information from the brain, unfiltered by the your questions. This free flow can be used to supplement questions you plan to ask

III. Conduct the interview

- Encourage the interviewee to tell their story without questions or interruption. If they don't remember the day in question, then ask them *How do you normally do it?* This way you can avoid when employees report that they were conscientiously following procedure when the error occurs – when the facts are possibly quite different because they do not feel safe.
- Avoid questions that have *yes* or *no* answers (closed question)
- Encourage the interviewee to confine their comments to what they observed, avoid hearsay and avoid comments not in their personal knowledge or experience.
- Avoid leading questions which unintentionally tells the interviewee how to respond and make it difficult for them to answer honestly (e.g. I suppose the result was called immediately, wasn't it?)

IV. Close the interview

- Check to make sure that all necessary information has been obtained, if not, ask the final questions
- Ask the interviewee if they have any further comments or questions
- Ask if there is anyone else who has insight into the problem
- Thank the interviewee and invite them to contact a team member with additional information if necessary.

V. Complete the documentation and analysis

- Finalize your notes so that anyone else reviewing your interview can understand what transpired
- After verifying records, determine if they know the right way to do it (**Human Error** – yes they know OR **Competency Issue** – no they do not)

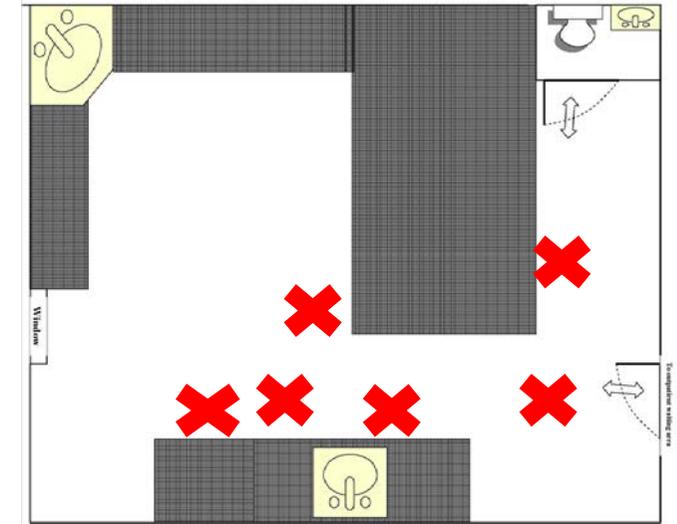
Photographs – Refer to the table portion entitled, *Understanding the Problem*.

Pictograms- Symbols are used to represent a concept, object, activity, place or event by illustration. It is a form of writing in which ideas are transmitted through drawing. Different symbols and colors can be used to add more information. When there is a spatial component to the problem, the pictogram may provide the insight the RCA team needs. Consider using a pictogram to:

- Map the locations where process steps are performed;
- Map the frequency of occurrences within a physical space.

The Steps in Brainstorming

1. Explain the rules
 - Do not discuss, criticize, or evaluate ideas during the brainstorming session .
 - Hunches are acceptable and no proof is needed.
 - All ideas are accepted during this process, the filtering of ideas will come later.
2. State the situation or problem referring to the substantiating evidence (e.g. This is what we know....).
3. Post the topic and known facts on a flipchart or whiteboard so that people can refer to them.
4. Allow participants to launch ideas according to the type of approach used.
 - Structured – each person in turn launches one idea. This approach ensures equal participation, but is less spontaneous and may limit the possibility of building on one another’s ideas.
 - Unstructured – everyone freely launches ideas and enables the building on one another’s ideas . This approach is very spontaneous, but it is often more confusing and can lead to one or more persons dominating the activity.
5. Write down every idea launched.
6. Allow the flow of ideas to stagnate once because the launching on more ideas will usually pick-up again.
7. Close the process when new ideas are only a reformulation of previously launched ideas or few new ideas are evident.
8. Narrow the causes to the most significant since not all these causes are of equal importance. Some of them will be outlandish in the spirit of brainstorming, and some will only be loosely connected to the problem.
9. Combine and group the remaining ideas. Consider grouping the ideas using a Cause-and-effect diagram. This will help identify what is needed for the next step, the collecting of evidence., by highlighting what documents and records to review, what to observe, what to measure, and who to interview.



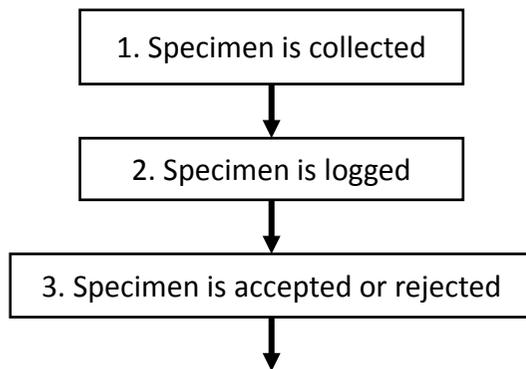
Brainwriting Instead of launching (shouting out) possible causes, the causes are written by the participants, This approach is useful when the topic is of a sensitive nature or the anonymity of the participants must be protected. The only difference between brainstorming and brainwriting is in the way ideas are recorded. 2 ways to record the ideas are presented as follows:

1. Ideas are written on a number of whiteboards or flipcharts. The participants circulate among them, adding related ideas or expanding on the existing ideas.
2. Ideas are written on small cards and circulated among participants, who add related ideas or expand on the existing ones.

The Steps in Process-Step Variation – When reviewing the process map of the failed process, one can brainstorm causes of the problem in conjunction with the step’s activity.

1. Create a plenary process map of the failed process, which was identified during Step 2: *Understand the Process* of the rca process. The plenary map can be either recreated onto a white board or flipchart, or projected onto a screen.
2. Distribute copies or refer participants to the failed.
3. State the situation or problem referring to the substantiating evidence (e.g. This is what we know....).
4. Post the topic and known facts on a flipchart or whiteboard so that people can refer to them.
5. Determine the boundaries of the process that will be under consideration for brainstorming. Consider making the end boundary the step where the detection of the problem occurred.
6. Beginning with the first box presented, by asking, *What failures could lead to our problem?*, to start the launching ideas. Write the ideas on the flipchart or white board. If the process map was recreated, then write the ideas next to that step. If no ideas are launched, then write *no ideas* for that process step.
7. Move on to the next step when ideas for the current step begin to halt. Continue in this fashion until you arrive at the ending boundary.
8. Narrow the causes to the most significant since not all these causes are of equal importance. Some of them will be outlandish in the spirit of brainstorming, and some will only be loosely connected to the problem.
9. Combine and group the remaining ideas. Identify what is needed for the next step in the RCA process, *Step 3: The Collecting of Evidence*, by highlighting what documents and records to review, what to observe, what to measure, and who to interview.

Specimen Collection Process



Specimen Collection Process

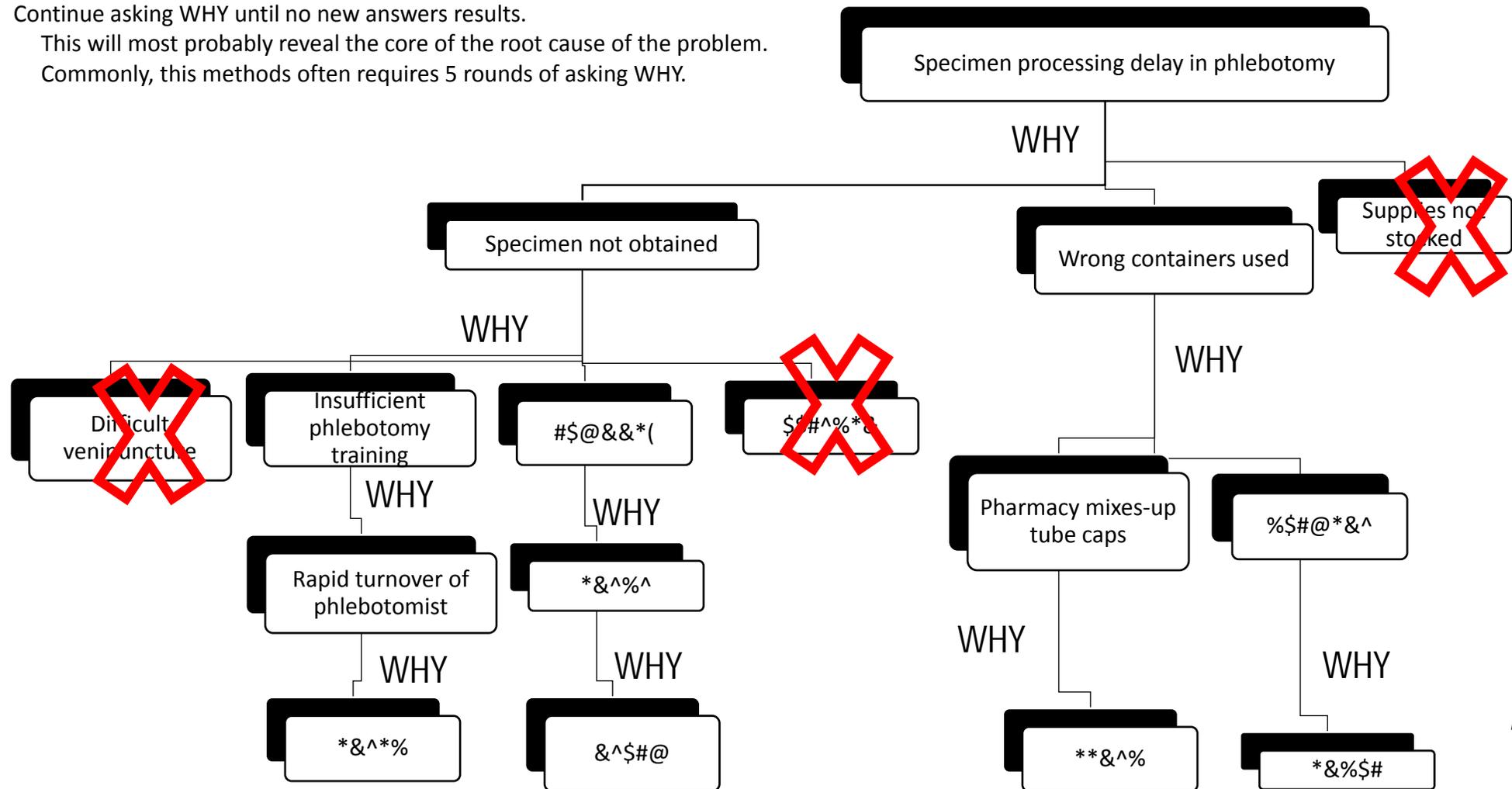
Brainstorming of Potential Causes

What could go wrong at each step leading to a delay in specimen processing in the phlebotomy section?

- Step 1
 - Unable to obtain specimens
 - Wrong containers are used
 - Supplies not stocked
- Step 2
 - Log book needs columns drawn
 - All staff performing phlebotomy, no one logging specimens
 - .
- Step 3
 - .

The Steps in Logic Tree- (WHY- WHY diagram) This diagram organizes different levels of causes in a similar fashion to a hierarchal chart, with the top level of the logic tree being the problem statement or a shorter description of the problem's symptoms. It is a way to document the idea of 5 WHYS that allows infinite depth in drilling down into the system being analyzed. Each level below the top level is developed by asking *why* or *how* the step above could have occurred. The responses to each *why* should sufficiently describe the causes (i.e. *inadequate training* instead of *training*). One major advantage of using flowcharts (sequential logic) or logic tree (hierarchal logic) is that each contains within it many more detailed causes, that if **eliminated** at the high level also eliminates all the micro level causes associated with it.

1. Determine the starting point of the analysis. The top level of the logic tree should be a shorter description of the problem statement.
2. Use brainstorming, brainwriting and other approaches to find causes at the level below the stating point.
3. Ask, *Why is this a cause of the original problem?*, for each identified cause to develop the next level.
4. Eliminate as many causes at that level as possible by placing an X over the cause.
5. Continue asking WHY until no new answers results.
 This will most probably reveal the core of the root cause of the problem.
 Commonly, this methods often requires 5 rounds of asking WHY.



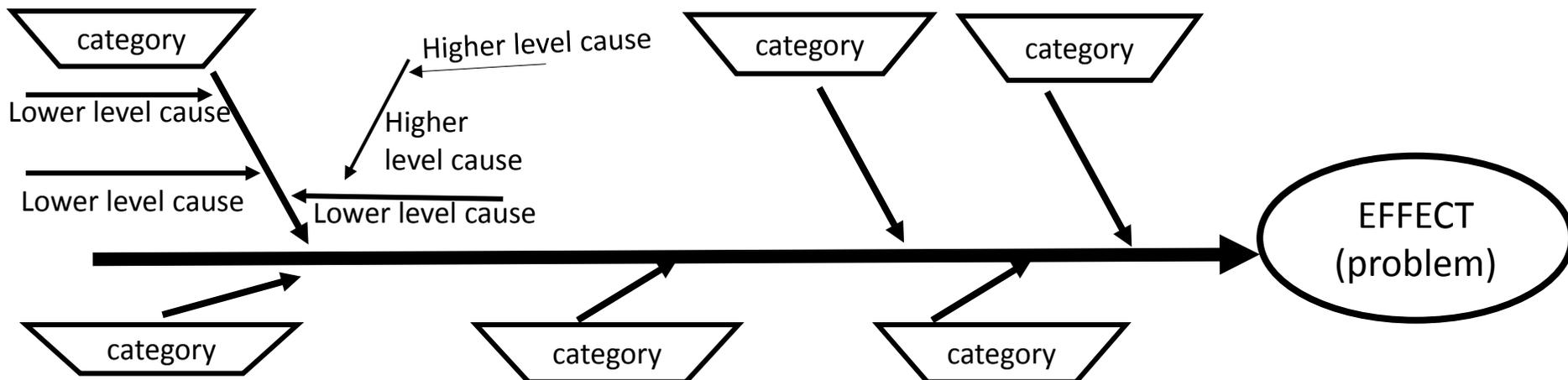
The Steps in Cause-and-Effect Diagram (Ishikawa Diagram, Fishbone Diagram) This diagram identifies many possible causes for an effect or problem by organizing causes in a graphic manner so that their relationships can be more readily understood. The brainstorming output makes the perfect input for cause-effect diagrams by immediately sorting ideas into useful categories.

Most typical categories (*bones*) used are the 6 Ms; however, virtually any category could be represented.

- **M**aterial (raw materials, components, , purchase orders, correctness of the material)
- **M**anpower (staffing numbers, training, communication)
- **M**achinery (production equipment, ancillary equipment, phone systems, computer systems, preventative maintenance, obsolescence)
- **M**ethod (procedures, work instructions, anything that defines the process or requirements, undocumented practices)
- **M**easurement (tools calibrated, accuracy, appropriate to job, devices used for testing, measuring, and verifying product)
- **M**ilieu / environment (temperature/humidity, safety, distractions, work space or workstation design, cultural climate)

If a cause can fit into 2 or more categories (and arguing is taking too much time), then put it both places. It is more critical to make sure an item is included than to make sure it is in the perfect spot. If a category does not work, mark it N/A (not applicable).

1. Clearly describe the problem or effect for which causes are sought.
2. Using a white board or flipchart, document the problem at the right end of a long arrow. Allow space above and below the arrow for the causes to be generated.
3. Identify the main categories of causes and write them on branches emanating from the large arrow.
4. Brainstorm and write all possible causes in the applicable area(s) of the chart. Use brief and succinct descriptions. Proceed through the chart one main category at a time. Write all causes that belong under more than one category in all relevant places.
5. Analyze the identified causes to determine the most likely root causes. You may decide to drill further into the higher level causes.

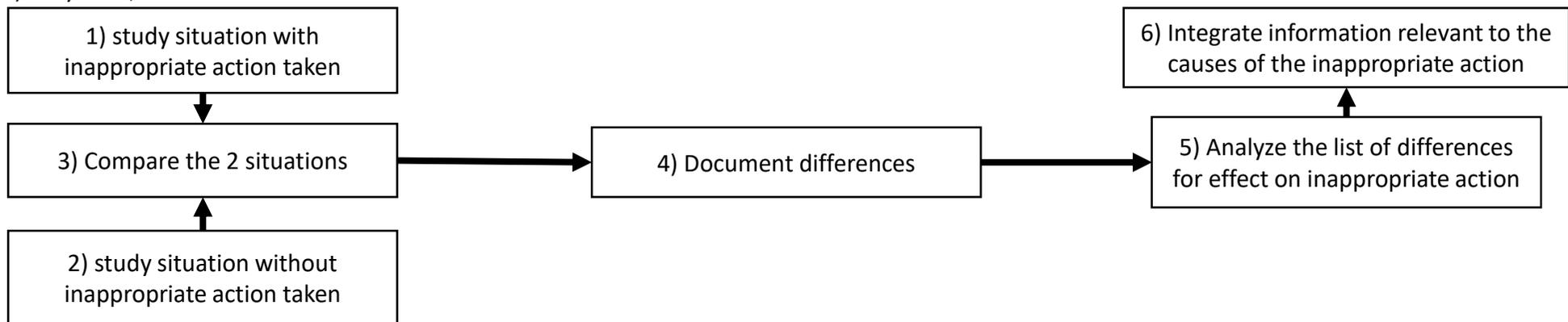


The Step in Using 5 Whys — 5 WHYS method can assist with drilling down to deeper causes.

1. Determine the starting point, either a problem or an already identified cause.
2. Ask Why? Besides *why*, you can ask such questions as, *If this happened, then what caused it?*, *What happened before?*, and *Why did that happen?*
3. For each new answer to the question, ask the question again, continuing until no new answer results.
4. Continue asking *why* until the answers you get in response no longer make sense or seem actionable (i.e. If you answered *gravity* to *Why did the patient fall?*, then go to an upper level cause you can address.)
5. As a general rule, this tool often requires 5 rounds of questioning *WHY*.

The Steps in Is - Is Not Matrix By comparing an activity that has been successfully performed to the same activity when it has been unsuccessfully performed, the table helps explore changes made in people, equipment, materials, methods, and so forth that may have contributed to the change in performance. Keep in mind that just because one of the areas may have changed does not indicate it is the cause, but it certainly raises it to a higher priority for focus. While using this tool, continuously ask 3 questions:

- 1) What was different about this time from all the other times that same task or activity was carried out without an inappropriate action?
- 2) Why now, not before?
- 3) Why here, not there?



1. Study the scenario with the inappropriate action. Write down the steps taken when that task was performed.
2. Consider a comparable scenario that did not have an inappropriate action. Write down the steps taken when that task was performed.
3. Compare the two scenarios
4. Document the differences using the matrix.
 - In the upper left corner, state the problem being analyzed
 - Complete the *IS* column by noting what is affected, where, when, who, and so on.
 - Complete the *IS NOT* column by noting what is NOT affected, where, when, who, and so on.
 - Compare the 2 columns for anything odd or that stands out and note this information in the *Difference* column.
5. Analyze how each element in the Difference column could be a cause of the problem.
6. For the possible causes identified, test them by checking if they could explain all items in the IS and IS NOT columns. Those items that do are causes that should be confirmed or denied using data.

Problem:	Is (does occur)	Is Not (does not occur when it could)	Difference / Distinction (therefore, what may explain the pattern)
What (e.g. condition, activity, equipment)			
When (e.g. occurrence, equipment status, schedule)			
Where (e.g. physical location, environmental conditions, process step)			
How (e.g. work practice, omission, extraneous action, out of sequence, poor process)			
Who (personnel involved, supervision, backgrounds and experiences contributing to knowledge and skills)			

Example Problem: Specimen processing delay in phlebotomy section	Is	Is Not	Difference / Distinction
What	Specimen rack not used	Specimen rack used	Specimen laid by log book
When	urgent	routine	Only urgents have problems
Where	Specimen is logged	Specimen is obtained	Occurs later in the process
How	Log book not prepared for the day's collection	Extra pages prepared to immediately begin logging	Log book prepared for day's collection
Who	Supervisor off day before	Supervisor present day before	Supervision availability day prior to delayed TAT

Sampling — When sampling is used to collect data to support other tools, remember to assess the nature of the population to be sampled. Decided on a suitable type of sampling approach that takes into account the homogeneity of the population, any clustering of data, cyclic or peak/trough times, etc. **10**

The Steps in Surveys - This tool is an excellent way to collect customer satisfaction data related to a problem, and determining customer needs and expectations. Don't forget, you staff are internal customers, too. Consider conducting your yearly customer satisfaction survey prior to your yearly strategic planning meeting to ensure your future efforts remain in alignment with customers needs.

1. Clearly define the objective of the survey and how the data will be used later.
2. Determine what information is required to achieve this objective.
3. Decide the format (written or verbal) and how the survey will be disseminated (email, fax, internet, focus group)
4. Develop the questionnaire, keeping in mind type and sequence of questions, grouping of questions, understandability, language, use of scales, comment sections, brevity, etc.
5. Test the questionnaire to ensure that all questions are easy to understand and can measure what they are intended to measure.
6. Identify the sample of respondents, and create an the action plan for conducting, collecting, and analyzing the survey.
7. Conduct the survey

The Steps in Tally Sheet – This tool identifies categories of what is expected and then records each time the event occurs. It can be used during interviews, observations, and review of records when expected categories can be clearly identified. Remember to always add a category entitled, *other*, so that significant occurrences are not overlooked due to the limitations set by the main categories. If other occurs frequently enough, it may deserve to be added to the tally sheet as a specific category.

1. Clearly define what events are to be recorded. Add the *Other* category to capture occurrences not easily categorized into any of the specified groups.
2. Define the period for data recording and suitable intervals.
3. Design the tally sheet to be used during data collection, allocating space for recording each event and for summarizing within the intervals and the entire recording period.
4. Ensure the staff understands the overall task and the reason for doing it, the events to be recorded, and how to record the events using the tally sheet.
5. Perform the data recording during the agreed period.
6. Analyze the data. Perhaps target events with unusually few or many occurrences.

Histograms – To produce a valid histogram, 30 points should be used. Interpret histogram patterns as follows:

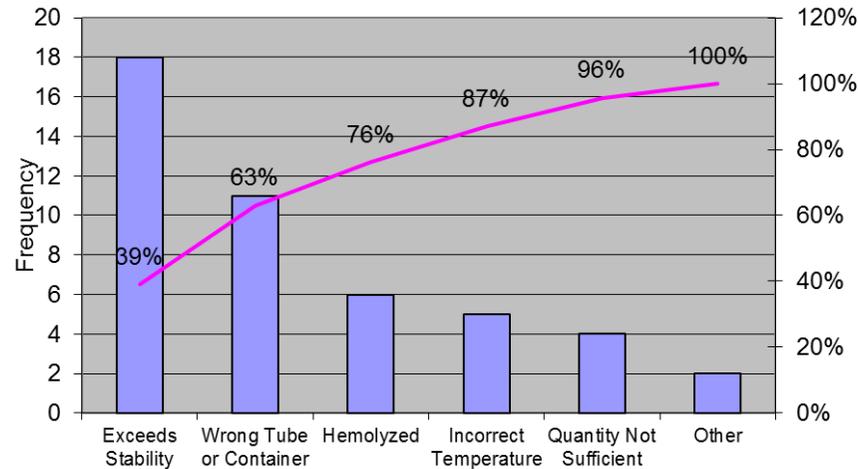
- One peak show the mean value of the process. If this peak is not centered, there often is a cause for it that may need further investigation.
- Two distinct peaks may be due to two different data sources, such as two shifts, two suppliers, etc.
- A comb-like pattern indicates that too many categories have been defined. Some categories are unable to capture data points, rendering the chart useless.

Pareto Chart – A Pareto chart is a bar graph. The lengths of the bars can represent frequency, quantity, time, or money and are arranged with longest bars on the left and the shortest to the right. In this way, the chart visually depicts which situations are more significant. The pink line represents the cumulative percentages that should reach 100% at the last bar depicted.

The Pareto principle states that most effects (80%) are the results of a small number of causes (20%). The Pareto chart graphically displays this skewed 80/20 distribution. To create a Pareto Chart, use the template included with your flash drive.

Example:

Category	Total
Hemolyzed	6
Quantity Not Sufficient	4
Wrong Tube or Container	11
Incorrect Temperature	5
Exceeds Stability	18
Other	2
TOTAL	46



Looking at the chart, we see that the *Exceeds Stability* category is tallied at 18 by measuring the height of the bar and reading it from the *Frequency* axis (primary y axis on the left). We also note that this same category comprises 39% of the nonconformities tallied ($18/46 = 0.39$). We see the pink line for the category beginning at 39% when we read it from the % axis (secondary y axis on the right).

Looking at the next tallest bar, the *Wrong Tube or Container* category, it reaches a frequency of 11 (y axis on the left). This category, along with the previous category (*Exceeds Stability*) comprise 63% of the nonconformities tallied ($(18 + 11)/46 = 0.63$), as seen when we read the pink line from the % axis located to the right. The *Wrong Tube or Container* category alone accounts for 24% ($63\% \text{ cumulative} - 39\% = 24\%$ or $11/46 = 0.24$)

When to Use a Pareto Chart

- When analyzing data about the frequency of problems or causes in a process.
- When there are many problems or causes and you want to focus on the most significant.
- When analyzing broad causes by looking at their specific components.
- When communicating with others about your data.

Scatter Plot - Refer to the table portion entitled, *Collect Evidence to Confirm or Deny Each Cause*.

