Performance Improvement (PI) Plan and Template

Approved and adopted

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by the

Maine Medical Association's
Committee on Physician Quality

Performance Improvement (PI) Plan and Template

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I. INTRODUCTION TO THE PERFORMANCE IMPROVEMENT (PI) PLAN AND TEMPLATE

A. GENERAL INTRODUCTION

This Performance Improvement (PI) plan guideline is in the form of a template. The template's design is relatively easy to use and customize. Current, evidence-based criteria for defining, advancing and sustaining performance improvement strategies have been incorporated into the document, as well as suggested forms and analytical tools. The template may be used in various settings.

Organizations may use this PI plan template in several ways:

- Those with well established, effective PI plans may wish to review this template and select components to incorporate into their pre-existing plan.
- Those with reasonably complete and effective plans may wish to use this template as the foundation for their new plan by incorporating selective elements of their pre-existing plan into this template.
- Those with no well-established, successful PI plans may elect to use this template to formalize their new PI plan.

The CPQ suggest that organizations that intend to use this template as the foundation for their new or updated PI plan proceed as follows:

- Designate a team of knowledgeable senior leaders, day-to-day managers, key clinical care and service directors/supervisors, front line staff, consumers, community leaders and consultants to carefully review the plan and make appropriate, adjustments in the template to produce a draft comprehensive, organization- specific PI Plan.
- Senior management should review the draft plan, make appropriate adjustments as needed, and approve the plan.

Each facility/program should conduct a formal review and revision (as needed) of its PI Plan at regular intervals, not to exceed every twelve (12) months.

B. HOW TO USE THE TEMPLATE

The user is prompted to insert [**INSERT HERE**] organization specific information in various locations throughout the template, and to remove [**DELETE**] unwanted information, to generate an up to date PI plan that meets the needs of the organization. To facilitate this process, text that is intended to remain as part of the PI plan appears in black ink color. Text that the individual organizations may insert or delete to customize this template appears as **black bold** ink color.

7) pharmacy consultant reports and drug regimen review
8) medication errors
9) unexplained weight loss
10) pressure ulcers/wounds
11) incontinence
12) nutrition, hydration and dietician reports
13) restraints
14) immunization card
15) infection control surveillance

B. SAMPLING: WHAT AND HOW TO SAMPLE

1. Reliable and valid tools
   a) Press - Ganey
   b) Holleran
   c) MyInnerview
   d) Gallop
   e) Web search for others
2. Sample by observation
   a) Real-time observation
      1) staff competency in relation to resident's plan of care
      2) medication pass
      3) infection control
      4) care plan compliance
      5) environmental safety
      6) others
   b) Record review

VII ANALYSIS OF DATA AND INFORMATION

A. PI PROCESS CYCLE *(See exhibits listing, page 17.)*

1. Plan Do Check Act (PDCA)
2. Strategic, Measurable, Achievable, Relevant, Timely (SMART)
3. PI Cycle: Data, Information, Knowledge, Plan, Act, Evaluate
4. Design Measure Assess Improve Control (DMAIC)

B. ROOT CAUSE ANALYSIS (RCA) *(See exhibit, page 26. - 32.)*

1. Definition: Root Cause Analysis (RCA) is a structured step-by-step questioning process that focuses on finding the real cause of a problem/incident/undesirable trend or event. RCA focuses on prevention, not blame, and should consist of a systematic search for "what really went wrong" and not "whose fault was it."

2. Purpose of the RCA:
    a) Identify the fundamental reasons why something undesirable happened
    b) Correctly identify the root causes so appropriate action plans can be identified and put in place
    c) Effectively develop an action plan that will prevent reoccurrence of the problem/incident/undesirable trend or event
3. Process of the RCA
    a) Data collection phase and analysis
        1) Begin RCA data collection as soon as possible following occurrence identification
        2) Include each individual involved in the occurrence in the data collection phase process
        3) Appoint a facilitator to guide the RCA process
        4) Document each individual's account of the problem/incident/ undesirable trend or event including conditions before, during and after the occurrence, personnel involvement including all actions taken, environmental factors and any other information having relevance to the problem/incident/undesirable trend or event. Documentation my be on a flip chart for all participants to view.
        5) Sample questions
            (a) Were facility/community procedures followed?
            (b) Was equipment in good condition?
            (c) Was lighting adequate?
            (d) What type of surface?
            (e) Was assignment excessive?
            (f) Was task part of normal duties?
            (g) Was individual trained?
            (h) Were housekeeping issues a factor?
            (i) Was task repetitive?
            (j) Was proper personal protective equipment (PPE) used?
    b) Analytical phase
        (1) Analyze data to identify the most likely causal factors utilizing the "Five Whys" technique. Keep asking "why" five or more times in order to get to the root cause of the problem.
        (2) Examples of "root causes" may include one or more of the following areas:
            (a) equipment
            (b) material

(c) procedure problem – not well defined
(d) policy problem
(e) personnel error-judgment errors
(f) design problem: process or system?
(g) training adequate
(h) external factors

(3) Summarize the findings of the data

c) Action plan

(1) Design and document an action/corrective plan

(a) identify an action plan for each cause

(b) identify what changes can be made to the system to prevent reoccurrence

(i) Redesigning systems may involve (not inclusive)

(a) policy and procedure changes
(b) staff education
(c) new equipment
(d) additional forms

(c) develop and document final action plan for administrative review

(d) assign responsibility for each action item with a time line

(e) institute follow up for reviewing completion and effectiveness of action items

d) Fish Bone Diagram *(See exhibit, page 25.-26.)*

e) Failure Mode & Effects Analysis (FMEA) *(See exhibit, page 35.)*

C. BENCHMARKING

1. Definition: Benchmarking is the process of comparing the cost, time or quality of one achievement against another achievement. The result may indicate an opportunity for making changes in processes and systems to improve outcomes.

D. PRESENTING DATA AND INFORMATION TO VARIOUS STAKEHOLDERS

VIII. CONFIDENTIALITY OF DATA, INFORMATION, FINDINGS AND REPORTS
(See definition, page 10.)

IX. EDUCATION/TRAINING

A. SENIOR MANAGEMENT

B. PI COMMITTEE MEMBERS AND PARTICIPANTS

C. ALL STAFF
D. RESIDENTS AND FAMILIES
E. COMMUNITY MEMBERS AND OTHERS

X. APPENDIX

A. DEFINITIONS

Administrative Review: the individual or group responsible for final decisions.

Benchmarking: the process of comparing the cost, time or quality of one achievement against another achievement. The result may indicate an opportunity for making changes in processes and systems to improve outcomes.

Brainstorming: an idea-generating technique for a group of people to solve problems:

- encourage unrestrained collective thinking
- all ideas are welcomed
- no single participant dominates the session

Cause and Effect Map: (Fishbone Diagram) offers a structured approach for identifying all possible causes of a problem.
See Exhibits, page 25. - 26., 33. - 34.

Confidential: data and information that includes all records and documents that are made available only to a few, select persons on a need to know basis. The ability of the organization to produce, analyze and maintain some performance improvement records as "confidential" is vital to the self-improvement process.

Culture: the established attitudes, beliefs, sentiments, formal and informal operating principles and behavior of the organization. **See culture change.**

Cycle of Performance Improvement (CPI):

the formal process of:

1. gathering meaningful data (relevant, timely, organized and accurate)
2. transforming the data into information through a process of evaluation and analysis
3. extracting the information that is most useful to obtain knowledge of the current systems strengths and weaknesses
4. developing a plan of action to wisely apply the knowledge gained to improve better results
5. sustaining implementation of the plan of action, and continuing evaluation of ongoing results by reapplication of the cycle

Various tools may help businesses apply the discipline required to follow the cycle of performance improvement, such as the following: **See Exhibits, page 17. - 38.**

1. Design, Measure, Assess, Improve, and Control (DMAIC) Tool
2. Plan, Do, Check, Act (PDCA) Tool
3. Fishbone Diagram
4. Root Cause Analysis (RCA)
5. Cause and Effect Map
6. Failure Mode and Effects Analysis (FMEA)
7. SMART Tool
8. Pareto Analysis Chart (PAC)

Dashboard: an informative presentation of performance improvement-related data, information, process adjustments and results, which may or may not be confidential.

Deficiency: the failure to meet recognized standards or requirements.

Design, Measure, Assess, Improve, Control (DMAIC): an approach to the cycle of performance improvement used to improve an existing process.

The basic methodology consists of the following five steps:

Step 1. DEFINE process improvement goals that are consistent with customer demands and the organizational strategy.

Step 2. MEASURE key aspects of the current process and collect relevant data.

Step 3. ANALYZE the data to verify cause-and-effect relationships. Determine what the relationships are, and attempt to ensure that all factors have been considered.

Step 4. IMPROVE or optimize the process based upon data analysis.

Step 5. CONTROL to ensure that any deviations from target are corrected before they result in defects. Pilot test the new process.

See Exhibit, page 18. - 20.

Fail Safe Methods: an implementation of methods and warnings to decrease probability of mistakes.

Failure Modes and Effects Analysis (FMEA): an approach to the **cycle of performance improvement** in the form of a procedure for analysis of potential failure modes within a system for classification by severity or determination of the effect of failures on the system.

Failure causes are any errors or defects in process, design, or item, especially those that affect the customer, and can be potential or actual.

Effects analysis refers to studying the consequences of those failures.

See cycle of performance improvement.
See Exhibit, page 35.

Fishbone Diagram: (Cause and Effect Map)

a tool that helps identify, sort and display possible causes of a specific problem or characteristics of a process. It graphically illustrates the relationships between a given outcome and the complex variety of factors that influence the outcome. **See cause and effect map. See Exhibits, page 25. - 26., 33. - 34.**

Incident:

is any event, occurrence, situation or circumstance, which is unusual or inconsistent with the policies, practices and routine operation of the community. An incident may be an accident or a situation, which may or may not result in bodily injury and/or property damage. Note: Physical or mental mistreatment of a resident is always considered an incident even when an actual injury has not occurred.

Interviewing:

a technique for identifying problems and collecting information. It can be used with staff, residents and family.

Mission Statement:

a brief description of a company's fundamental purpose that answers the question, "Why do we exist?". The mission statement articulates the company's purpose both for those in the organization and for the public.

Monitor:

to intermittently watch, check or observe for a particular purpose.

Near-miss:

an unplanned event or negative outcome that did not result in injury, illness, or damage - but had the potential to do so; such as when a fortunate break in the chain of events prevented a negative outcome. Although human error is commonly an initiating event, a faulty process or system invariably permits or compounds the harm, and should be the focus of analysis and improvement. Other familiar terms for these events are a "close call", or in the case of moving objects, "near collision".

Pareto Analysis Chart:

a bar graph used to arrange information in such a way that priorities for process improvement can be established. **See Exhibits, page 37. - 38.**

Plan Do Check Act (PDCA): one approach to the **cycle of performance improvement.** The PDCA cycle is a checklist of the four stages which you must go through to get from problem-faced to problem solved. The four stages are Plan-Do-Check-Act, and they are carried out in a cycle. **See cycle of performance improvement. See Exhibits, page 21. - 24.**

Problem: a deviation from expected, desirable results.

Process: an organized group of related activities that work together to transform one or more kinds of inputs into outcome(s) that are of value to customers. A system may contain multiple processes. **See system and protocol.**

Protocol: a formalized process. The term protocol is often applied to processes that involve clinical care assessments, activities and outcomes. **See system and process.**

Quality of Care: care and services that respect the individual's needs and choices, improve the likelihood of achievable clinical outcomes, and are consistent with evidence-based knowledge. **Quality of care** leads to **Quality of life**, the goal for long term care residents, which may be best measured by each individual resident.

Resident-centered: care and services that are respectful of and responsive to individual resident preferences, needs, and values to ensure that residents' values guide all clinical/service decisions.

Resident-directed: care and services that are provided at a time and in a manner that is directed and controlled by the resident.

Root Cause Analysis (RCA):	a structured, step-by-step, analytical problem solving process to help determine the fundamental (root) cause(s) of problems. This problem identification process helps performance improvement professionals avoid wasting time fixing "symptoms" of a deep rooted problem, and guides them through steps to identify the root causes. RCA is not about assigning blame. It is about preventing the reoccurrence of undesirable outcomes. **See Exhibits, page 27. - 32.**
Sample:	a selected part, section, or item that is believed to be representative of the nature of the whole from which it was taken.
Sentinel Events:	are relatively infrequent, clear-cut events that occur independently of a patient's condition that result in unnecessary outcomes for patients.
Standardized Process, Protocol or System:	one that is well defined and consistently followed without variation. **See system, process and protocol.**
Strategic, Measurable, Achievable, Relevant, Timely (SMART):	a way of assessing objectives to assure that they are written in a manner that identifies their strategic significance, are measurable, can be achieved, are relevant to the issues, and are timely to the needs of the organization. **See Exhibit, page 36.**
System:	a group of independent processes and people that together perform a common mission **See process and protocol.**
Values Statement:	are grounded in values and defines how people want to behave with each other in the organization. They are statements about how the organization will value customers, suppliers, and the internal community. Values statements describe actions that are the living enactment of the fundamental values held by most individuals within the organization. The values of each of the individuals in your workplace, along with their experience, upbringing, and so on, meld together to form your corporate culture.

Variation: a change in data, characteristics, process or function that may be caused by one or more of four factors. Before correcting for variation, performance improvement professionals will likely want to know the type of variation that occurred. The different types are as follows:

Common cause variation is a variation that comes from one or more elements inherent within the process.

For example: The expected process for medication delivery is that the off-premises pharmacy will deliver medications to the facility daily between 4 and 6 pm. Because the defined process has multiple variables that may influence the actual delivery time, some variation outside of the expected range (two hours) may occur and may be attributed to process itself.

Special cause variation is variation that comes from a special circumstance.

For example: The driver of the car transporting the medications from the pharmacy to the facility is involved in a serious accident, the car can not be driven, another/ driver is dispatched, and the delivery of medications is delayed by three hours. In this example, the variation was due to special cause – the accident.

Structural variations are regular changes caused by seasonal adjustments or long term trends.

For example: Over time, the traffic congestion along the route driven by the pharmacy delivery vehicle increased to a degree that the medications scheduled for a 6 pm delivery are not delivered until 6:30 pm most days. The long term trend of increased traffic was a structural variation.

Tampering is a misguided attempt to adjust a process to otherwise correct minimal variation that is within acceptable limits.

For example: The pharmacy delivery schedule is working well and medications always arrive between the allotted times – 4 to 6 pm. However, the weekend pharmacy dispatcher decides to "improve" services and move up the delivery time to between 4 and 5 pm, by directing the driver to take a different road route. The new route caused the driver to get lost and caught in evening rush hour traffic, and the medications did not arrive until 7 pm. The dispatcher "tampered" with a process that was working within expected standards, and made it worse.

Vision Statement: sometimes called a picture of your company in the future but it's so much more than that. Your vision statement is your inspiration, the frame work for all your strategic planning. Unlike the mission statement, a vision statement is for you and the other members of your company, not for your customers or clients. **See mission statement.**

B. EXHIBITS, FORMS AND TOOLS

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DMAIC AND TOOLS

DMAIC stands for: **Define, Measure Analyze, Improve and Control**

Represents the five steps, starting with the analysis through to project completion.

	STEP	OBJECTIVE	DESCRIPTION	TOOLS TO USE
1.	**DEFINE**	What is the problem?	• Identify the improvement opportunities and scope (what will be included) of the project	• Benchmarking • Pareto • Gap analysis • Process Map (current process)
2.	**MEASURE**	How are we doing?	• Analyze the process to identify the problem • Define the expected outcome	• 5 Whys • Check and Tally Sheets • Actual timings against expected • Process Map (expected process)
3.	**ANALYZE**	What is wrong?	• Identify the root causes of the problem	• 5 Whys • Benchmarking • Root cause analysis • Fishbone diagram • Brainstorming (see root cause analysis) • Interviewing (use the 5 whys)
4.	**IMPROVE**	Fix the problem	• Refine and prioritize the improvement opportunities • Initiate the project, create a plan and project manager	• Project plan • Project management
5.	**CONTROL**	Maintain the gains and publish results	• Control measures put in place to ensure results are achieved and maintained. • Evaluate the results at the end of the project (and possibly again at a later date). • Publish results and thank participants	• Sustainability • Continuous Improvement

DMAIC AND TOOLS

Define, Measure Analyze, Improve and Control

Follow the five steps, starting with the analysis through to project completion.

Problem:				
	STEP	**OBJECTIVE**	**DESCRIPTION**	**TOOLS TO USE**
1.	**DEFINE**			
2.	**MEASURE**			
3.	**ANALYZE**			
4.	**IMPROVE**			
5.	**CONTROL**			

Steps of DMAIC

Define, Measure Analyze, Improve and Control

Follow the five steps, starting with the analysis through to project completion.

Step 1 - DEFINE - The problem.

1. This stage is about identifying the improvement opportunities and identifying the scope (e.g. what will be included) of the project.
2. The business requirements and the customer's requirements are established.
3. If there are any shortfalls between the requirements and the process the analysis moves to the next stage.

Step 2 - MEASURE - How are we doing?

1. The process is analyzed. And the expected performance is determined.
2. Prepare a process map.

Step 3 - ANALYZE - What is wrong?

1. The root causes of the problem are identified.
2. Various analysis is used to obtain data to help work towards a solution.

Step 4 - IMPROVE - Fix the problem

1. The improvement opportunities are refined and prioritized.
2. A business case is usually completed which provides details of the solution and the benefits to be gained. If there is more than one solution the business case would usually include details of all solutions and the benefits that each would provide.
3. The pros and cons of each will usually be included together with recommendations for the best solution.
4. When the solution is agreed and receives approval to proceed, a project is initiated, implementation is planned and the project is managed.

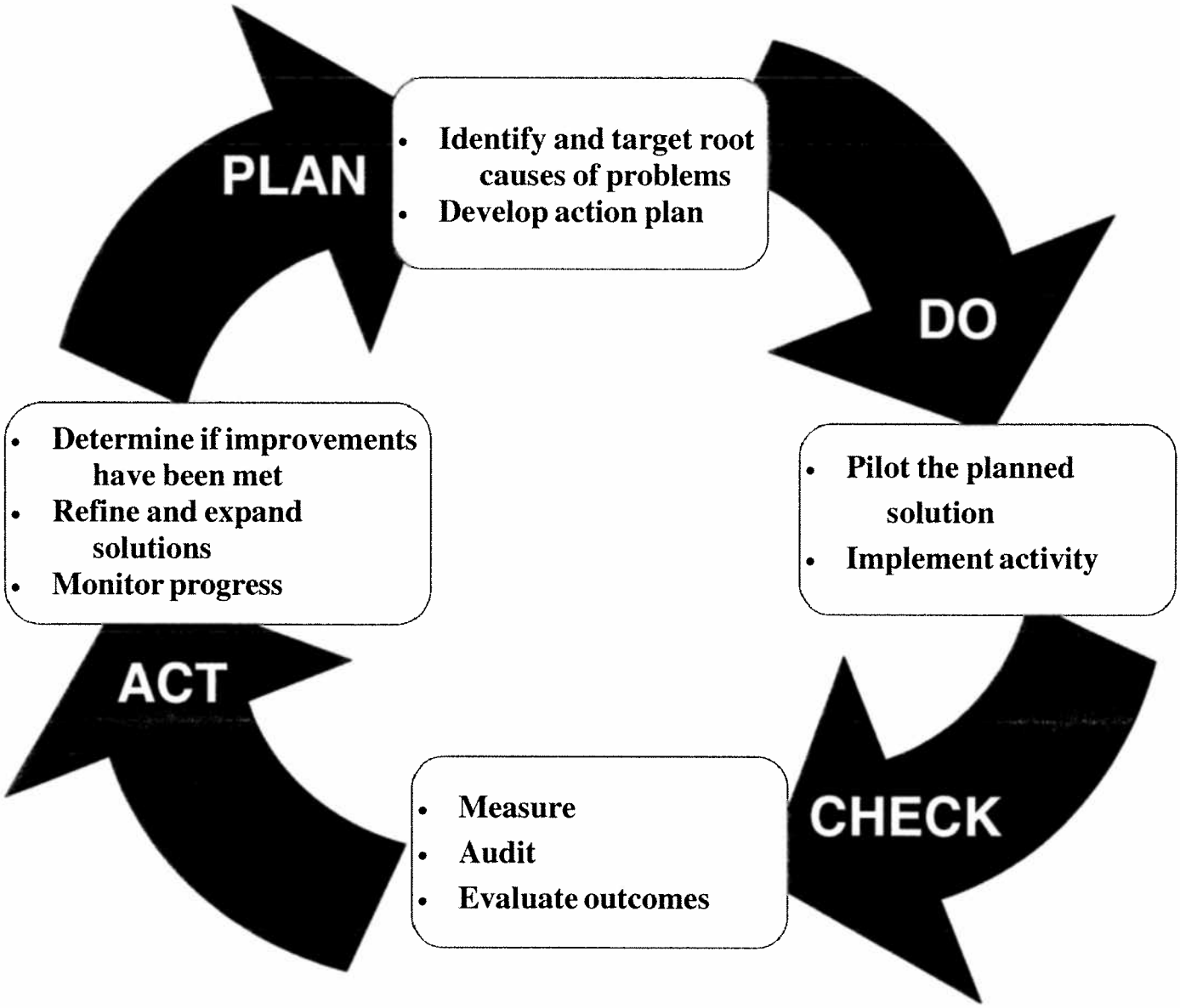
Step 5 - CONTROL - Maintain the gains and publish results

1. Control is maintained throughout the project to ensure the desired outcomes are achieved.
2. Atthe end of the project the process is measured again to ensure the expected outcomes have been achieved and checks made to ensure the improvements can be sustained.
3. A further evaluation may be carried out several weeks or months after implementation to check that the expected improvements have been sustained.

PDCA CYCLE

Plan, Do, Check, Act

Follow the four steps, starting with the analysis through to project completion.



PDCA TOOL

PDCA stands for: **Plan, Do, Check, Act**

Represents the four steps, starting with the analysis through to project completion.

Problem example: Mrs. K's recent fall

PLAN	DO	CHECK	ACT
Fall risk assessment is completed timely and accurately • Admission assessment • Complete within eight hours of admission • 14 day post admission • 30 day post admission • Post fall • Significant change	All nurses responsible for admitting a resident will be in-serviced on the fall risk assessment • Euphemize on eight clinical conditions • Review of newly admitted resident's hospital course of stay • Medication reconciliation • Time frame in which to complete the fall risk assessment Admitting nurse completes assessment within the shift the resident is admitted Supervisor of the following shift will review fall assessment for completion and accuracy	• Admitting nurse completes fall risk assessment • Time frame fall risk assessment • was completed • Accuracy to the completed fall risk assessment Change of shift Lunch time dining room checks Residents returning from therapy alarm checks Audit?	• Reduction in number of falls • Continue to monitor • Continue random checks • Continue education of staff • Discuss and report any changes to the team

PDCA TOOL

Plan, Do, Check, Act

Follow the four steps, starting with the analysis through to project completion.

Problem:

PLAN	DO	CHECK	ACT

Miscellaneous:

Steps of PDCA

(Plan, Do, Check, Act)

Follow the four steps, starting with the plan through to action and project completion.

Plan Step:

1. *Recognize the problem and establish priorities.* Problem may be outlined in very general terms based on information from several sources.
2. *Form the problem-solving team.* Interdisciplinary teams of individuals close to the problem are best.
3. *Define the problem and its scope clearly.* Who, What, Where and When. **Pareto Analysis** can be useful in defining the problem. **See exhibit on page 37. - 38.**
4. *Analyze the problem/process.* Process flowcharts can be useful a useful tool.
5. *Determine possible causes.* Cause-and-effect diagrams are helpful in identifying root causes of a problem. Data from the diagrams can be organized using check sheets, scatter diagrams, histograms, and run charts.
6. *Identify possible solutions.* Brainstorm to find solutions. Avoid the temptation to propose quick, immediate fixes. Goals should be specific, measurable, achievable, and realistic.
7. *Evaluate potential solutions.* Focus on solutions that address root causes and prevention of problem occurrence. Solutions should be cost-effective. Achieving group consensus is important.

Do Step:

1. Implement the solution or process change
2. Monitor results and collect data

Check Step

1. Review and evaluate the result of the change
2. Measure progress against milestones
3. Check for any unforeseen consequences

Act Step - **If successful,**

1. Standardize process changes
2. Communicate to all involved
3. Provide training in new methods

Fishbone Diagram

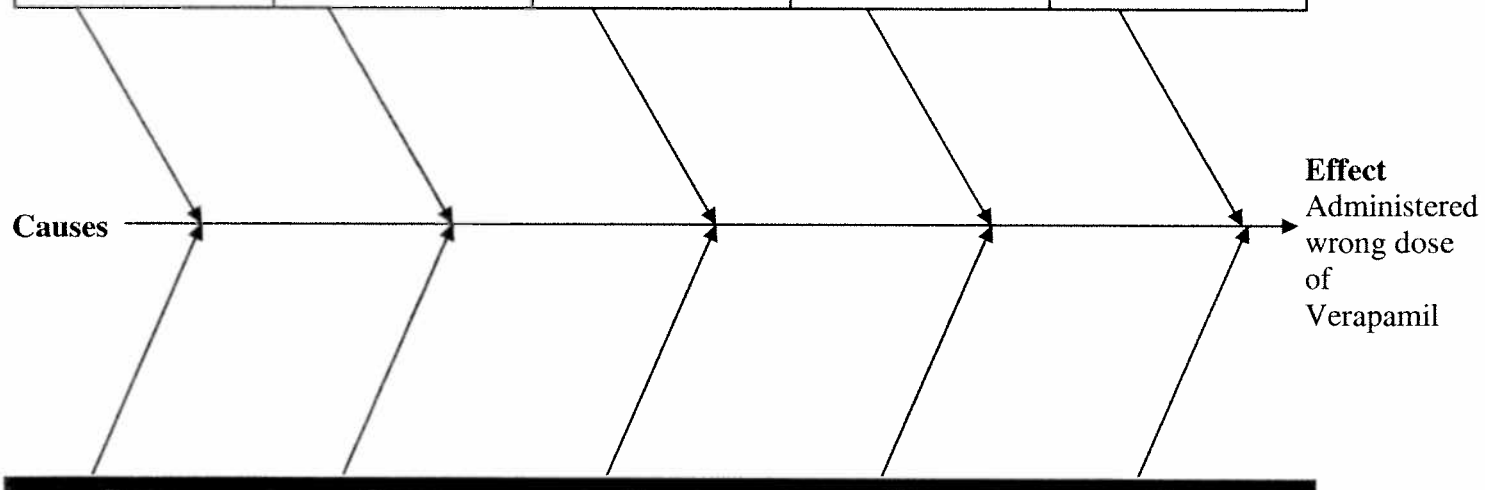
Fishbone Template for Root Cause Analysis

What are Fishbone Diagrams? These diagrams are used in identifying and organizing the possible cause of a problem. Cause-effect diagrams are also called Ishikawa diagrams after their creator, Dr. Kaoru Ishikawa. They are also referred to as fishbone diagrams because they resemble the skeleton of a fish, with a head, spine and bones.

A Fishbone Diagram is a visual illustration that clearly shows the relationship between a topic and the various factors related to it. The shape of the diagram looks like the skeleton of a fish. The bones of the fish represent factors that have been combined or synthesized to form categories. The categories, in turn, come together to form the topic that is depicted in the head of the fish.

Problem example: Mrs. K's Verapamil order

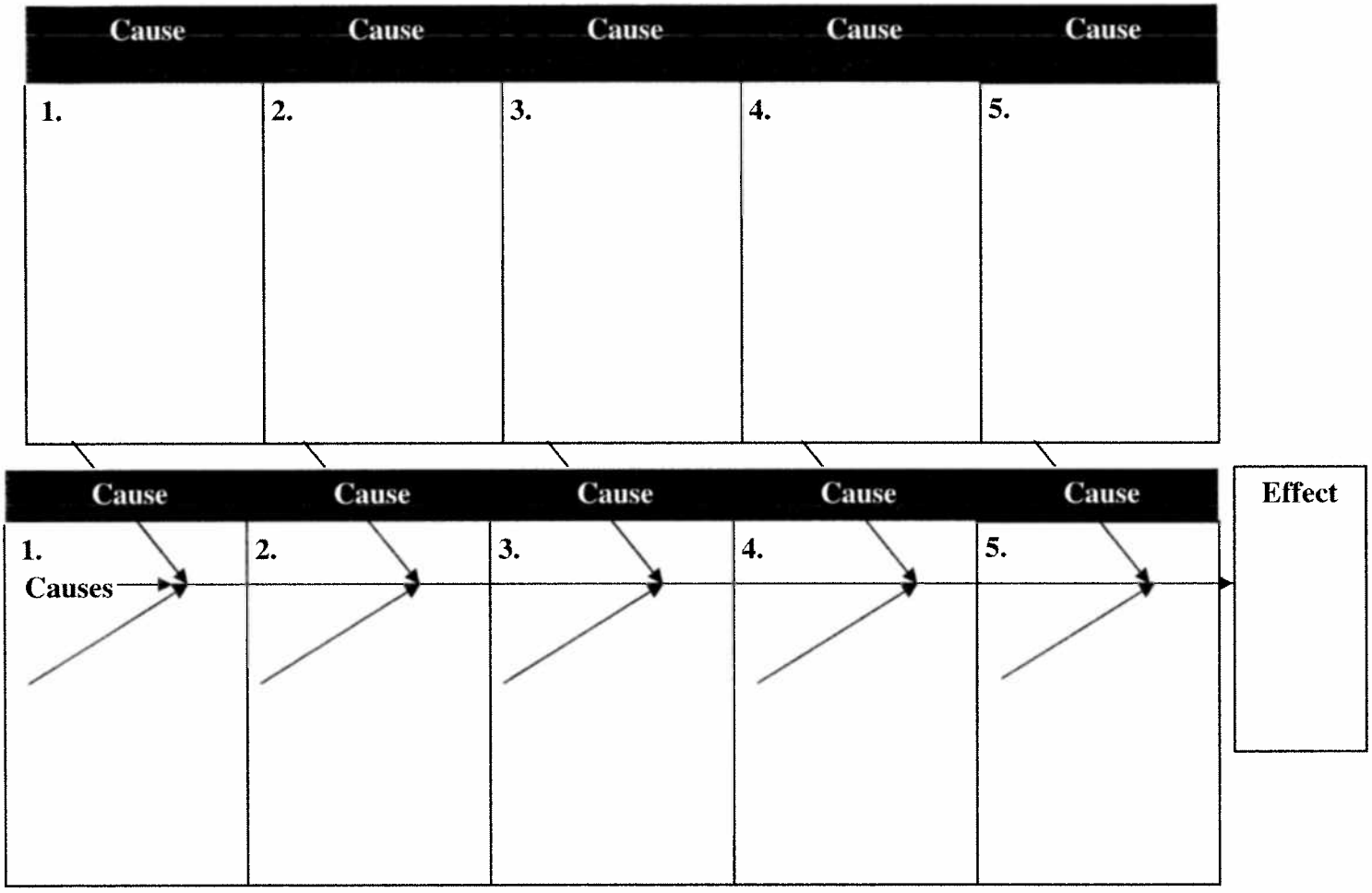
Cause	Cause	Cause	Cause	Cause
1. Transfer Form was incomplete	**2.** Transfer Order was not clarified	**3.** Hospital POS or MAR were not checked	**4.** Pharmacy did not question incomplete order	**5.** Pharmacy sent immediate release form of drug



Cause	Cause	Cause	Cause	Cause
1. Pharmacy instructions for dosage were wrong	**2.** Nurse changed MAR to reflect pharmacy instructions	**3.** Nurse did not check original order (POS) prior to administering medication	**4.** Nurse did not have adequate knowledge of medication being administered	**5.** Policies were not followed

Fishbone Template for Root Cause Analysis

Problem:



Miscellaneous:

Root Cause Analysis (RCA)

Template for Root Cause Analysis

A. **WHAT IS A ROOT CAUSE ANALYSIS (RCA)?** Root cause analysis (RCA) is a class of problem solving methods aimed at identifying the root causes of problems or events. The practice of RCA is predicated on the belief that problems are best solved by attempting to correct or eliminate root causes, as opposed to merely addressing the immediately obvious symptoms. RCA is a critical feature of any safety management system because it enables answers to be found to the questions posed by high risk, high impact events (including near misses) — what happened, why it occurred, and what can be done to prevent it from happening again.

B. **WHEN SHOULD RCA USED?** RCA is normally only performed on high risk, high impact events, such as sentinel events. A reportable near miss sentinel event is managed using the same processes as an actual event.

Sentinel Events are relatively infrequent, clear-cut events that occur independently of a patient's condition that result in unnecessary outcomes for patients. **See definition, page 15.**

An incident is any event, occurrence, situation or circumstance, which is unusual or inconsistent with the policies, practices and routine operation of the community. An incident may be an accident or a situation, which may or may not result in bodily injury and/or property damage. Note: Physical or mental mistreatment of a resident is always considered an incident even when an actual injury has not occurred. **See definition, page 13.**

Note: All incidents should be reported, investigated, and recorded especially if there was no adverse outcome.

C. **WHAT ARE THE TIMELINES FOR RCA?** The RCA processes should be investigated as soon as allowable after an incident. The more time elapsed, the less reliable the account of events by people involved and important information may no longer be available.

1. A RCA team should be convened within two working days of an incident.
2. A RCA report should be signed off within two calendar months of commencing the investigation.
3. Notify the appropriate authorities (insurance companies, government agencies, and internal departments) of the occurrence of all sentinel events per their regulations. Report investigation findings and submit a risk reduction action plan.

D. FIVE MAJOR RCA INVESTIGATION PRINCIPLES:

1. *Thoroughness:* a complete review of all possible causes is required. Focus on systems and processes (not individual performance)
2. *Fairness:* in terms of involvement of all staff associated with the incident. (be fair, thorough and efficient)
3. *Efficiency:* the time taken to undertake the investigation should be consistent with the significance of the problem being investigated. (focus on problem solving)
4. *Independence:* include independent team members to help reduce the impact of bias (overcome the fear to present information others may not want to hear)
5. *Use a scale of effectiveness to develop recommendations.* (use recognized analytical methods)

E. TEN MAJOR STEPS IN A RCA INVESTIGATION:

1. Verify the incident and define the problem
2. Commission the RCA investigation
3. Map a timeline (event and causal factor chart)
4. Identify critical events
5. Analyze the critical events (cause and effect chart)
6. Identify root causes
7. Support each root cause with evidence
8. Identify and select the best solutions
9. Develop recommendations
10. Write and present the report

F. COMMISSIONING A RCA INVESTIGATION: The ultimate responsibility for responding to serious incidents lies with an executive position who has primary responsibility for the delivery of clinical care. This individual becomes the executive for the RCA program in verifying the incident and defining the problem.

To brief the commissioning executive and focus the RCA effort, the RCA coordinator must first define and determine the level of significance of the problem that is to be investigated.

Defining the problem provides a clear understanding of:

1. the problem the RCA team is required to address
2. the scope of the investigation
3. the consequences of the incident

G. FORMING THE RCA TEAM

1. A *small group of staff*, which has expertise either in RCA methodology or in an area relevant to the incident, conducts the RCA investigation. Organizations should try to keep the size of the team manageable. Between three and six members is ideal.
2. A RCA *facilitator* is responsible for facilitating the RCA investigation. This includes forming the team, mapping the event, ensuring the team meetings occur and follow the agreed process, and facilitating team meetings. This person might also be the RCA coordinator.
3. A RCA *team leader* is usually the head of a clinical unit or another staff member with a recognized leadership role. Their role involves ensuring clinical participation, supporting the team facilitator at meetings, and ensuring the clinical content is relevant and appropriate.
4. RCA *team members* are those staff who participate in the team meetings and assist with data gathering. They provide relevant expertise and should be able to provide impartial input. Team members do not need to be clinical staff. Organizations should involve staff who are familiar with work practices and systems (for example, biomedical engineering, security, consumer liaison, and administrative staff).
5. *Others:* Involve staff who were directly involved with the incident only if their ability to remain objective is not compromised.

H. WRITING ROOT CAUSE STATEMENTS

Root cause statements are written as conclusions. Conclusions can be either:

1. Cause and effect statements

   Example: Cause and effect - The lack of staff training on the management of patients with chest pain resulted in the patient being discharged without appropriate investigations being completed, which contributed to the patient's readmission and subsequent cardiac arrest.

2. Prophetic statements (predictions)

   Example: Prophetic - The unavailability of guidelines for the management of chest pain in the emergency department will continue to contribute to the delivery of sub-optimal care.

I. THE FIVE RULES OF CAUSATION

1. Causal statements must clearly show the cause and effect relationship. When describing why an event has occurred, show the link between the root cause and the undesirable outcome.
2. Negative descriptors are not used in causal statements. To force clear cause and effect descriptions (and avoid inflammatory statements) do not use negative descriptors.
3. Each action cause must have a corresponding conditional cause. For every human error in the causal chain, there must be a corresponding condition cause that combined to contribute to the undesired effect.
4. Each procedural deviation must have a preceding cause. Identify the cause of a procedural violation, not the violation.
5. Failure to act is only causal when there was a pre-existing duty to act. The duty to perform might arise from standards and guidelines for practice or other duties to provide patient care.

J. PREPARING RECOMMENDATIONS AND REPORTS

1. Formulating Recommendations

a) The investigation team writes recommendations after the solutions have been evaluated for the likelihood of their effectiveness. Recommendations are suggested actions that management will consider after the investigation report has been presented to the executive sponsor.

b) The RCA team will need to consider who to consult when developing recommendations and be aware of the wider system implications of actually putting recommendations in place. To be credible, recommendations should be evaluated against:

1) the root cause (conclusion) statement
2) the RCA method used
3) the level of associated risk
4) the hierarchy of control
5) achievability
6) the perceived value to the organization

2. Writing a RCA report

a) Reports are written to communicate to management the findings, conclusions and recommendations pertaining to the initial problem the RCA team was requested to investigate. The report's comprehensiveness depends on the significance of the investigation findings. The report is written after recommendations have been evaluated for effectiveness.

b) Regardless of the reporting format chosen, the report should include these three elements:

1) executive summary
2) event and causal factor chart
3) conclusions, supporting evidence and recommendations

K. RCA POST-INVESTIGATION RESPONSIBILITIES

After signing off the RCA report, it is

1. the RCA *team leader's* responsibility to:
   a) develop and implement a risk reduction action plan to manage the risks identified by the RCA team
2. the RCA *program coordinator's* responsibility for:
   a) arranging for the findings to be presented to the people involved in the incident
   b) ensuring organizational reporting requirements are met
   c) completing governmental reporting requirements
3. the *team executive* is responsible for:
   a) ensuring a risk reduction action plan is prepared and implemented
   b) monitoring the progress and outcomes of risk mitigation strategies

L. DEVELOPING THE RISK REDUCTION ACTION PLAN

The causal statements developed in the RCA investigation need to be converted into risk statements. This should be done in conjunction with staff responsible for organizational risk management. It requires an assessment of the level and analyses of the risk. The risk reduction action plan should include a description of:

a) who is accountable for the risk
b) what action is to be taken
c) who is responsible for the action
d) by when the action is to be completed
e) a measurable performance target

M. RCA DOCUMENT MANAGEMENT

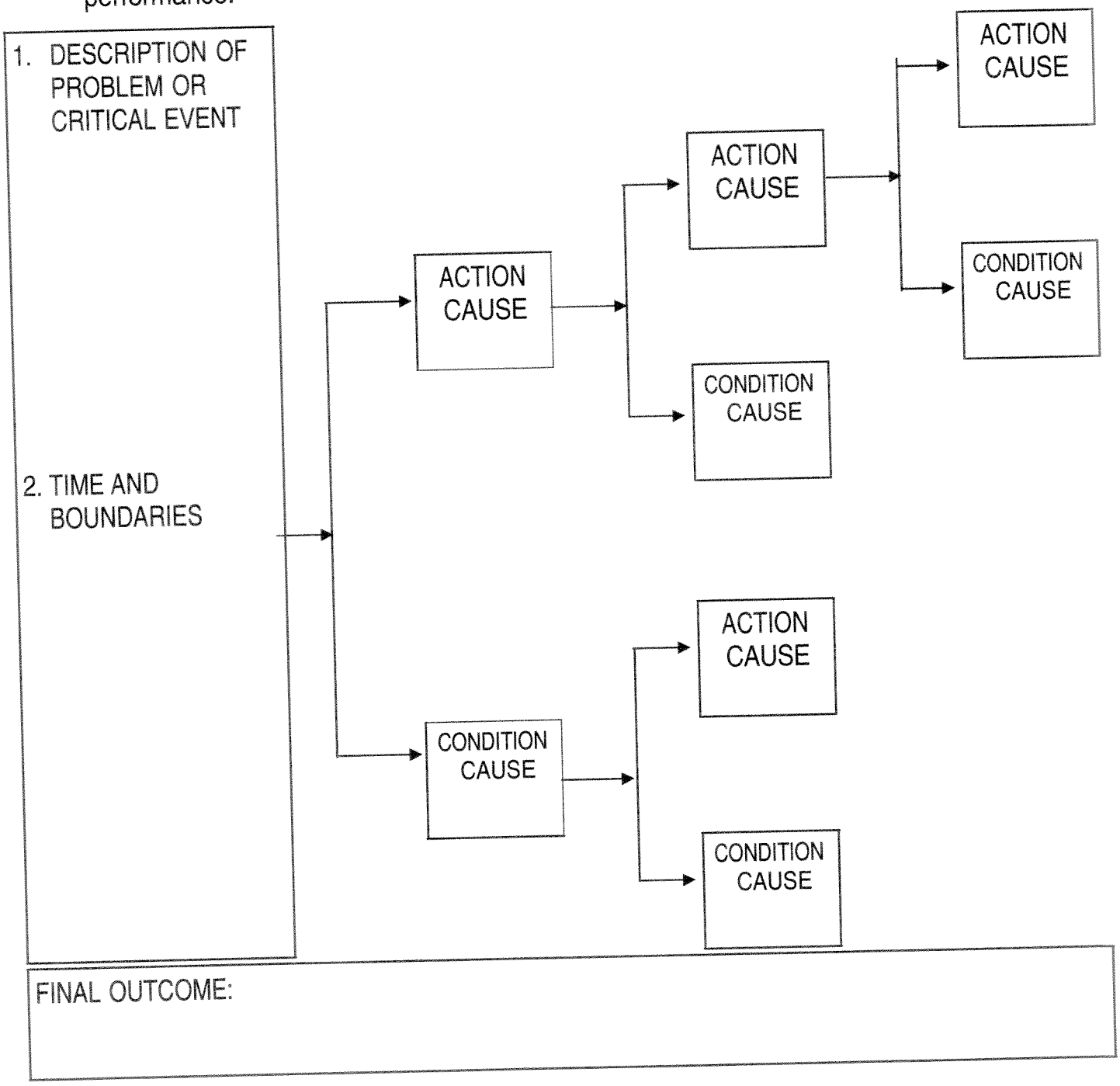
(Note: If investigations were not protected by legal or professional privilege, all documents are subject to disclosure)

1. Keep a RCA investigation register to provide a record of the investigations undertaken, when they were done, what problem they were commissioned to solve, and which staff participated.
2. Keeping a copy of all completed reports, risk reduction action plans and the outcomes achieved is necessary in case a similar problem occurs and the organization needs to identify which strategies were ineffective.
3. Documenting risk reduction action plans in a risk register or other action tracking system is necessary to ensure the monitoring and outcome loop is closed.

CAUSE AND EFFECT MAP

Cause and Effect process mapping shows small steps of a sequence of events leading to an end result. The process is:

1. Identify the PROBLEM or CRITICAL EVENT. Start *up-stream* from the perceived area of interest and move *down-stream* a bit beyond your area of interest.
2. Identify the steps (ACTION CAUSE) leading to CONDITION CAUSES of the problem or critical event.
3. Set enough time and boundary levels for each action to achieve a goal without limiting the performance.



CAUSE AND EFFECT MAP

The four stages of a cause and effect map helps you to think through causes of a problem or critical event thoroughly. Their major benefit is to systematically consider all possible actions and causes, rather than just the most obvious. Follow these four stages to solve a problem or critical event:

1. **STAGE 1: IDENTIFY THE PROBLEM**
   a) Write down the exact problem in detail (CRITICAL EVENT).
   b) Where appropriate, identify who is involved, what the problem is, and when and where it occurs (DESCRIPTION OF PROBLEM OR CRITICAL EVENT). Leave space to develop action cause and condition cause ideas.

2. **STAGE 2: WORK OUT ALL MAJOR FACTORS INVOLVED**
   a) Next, identify the factor(s) or ACTION CAUSE(S) that may contribute to the problem.
   b) Draw lines off the spine for each factor or ACTION CAUSE, and label it. These may be people involved with the problem, systems, equipment, materials, external forces, etc.
   c) Draw out as many possible factors or ACTION CAUSE(S) as possible.
   d) If you are trying to solve the problem as part of a group, then this may be a good time for some brainstorming. **See brainstorming, page 10.**

3. **STAGE 3: IDENTIFY ALL POSSIBLE CAUSES**
   a) For each of the factors or ACTION CAUSE(S) considered in stage 2, brainstorm possible causes of the problem or critical event that may be related to the factor (CONDITION CAUSE).
   b) Show CONDITION CAUSES as smaller boxes coming off the factors or ACTION CAUSE(S). Where a cause is large or complex, break it down into sub-causes. Show these as lines coming off each cause line.

4. **ANALYZE YOUR DIAGRAM:**
   a) By this stage you should have a diagram showing all the possible causes of your problem or critical event of which you can think.
   b) Depending on the complexity and importance of the problem or critical event, you can now investigate the most likely causes further. This may involve setting up several investigations, carrying out surveys, etc. These will be designed to test whether your assessments are correct.

FAILURE MODE EFFECT ANALYSIS (FMEA)

A Failure Mode Effect Analysis (FMEA) is a tool for proactively evaluating processes and/or products and identifying ways to prevent defects. FMEA allows the project to proactively identify potential problems and implement avoidance or mitigation strategies to minimize any potential adverse effect on the program. *FMEA spots problems before a solution is put into action.*

1. IDENTIFY ALL POTENTIAL AREAS OF FAILURE FOR A PROCESS.

a) This approach most often involves multi-discipline teams, sometimes with customer involvement, who will use techniques such as brainstorming to identify all the potential areas of failure for a product or process.

b) From this data the team can then identify the major risks to the product or program and can develop the most appropriate mitigation and/or avoidance strategies.

2. FAILURE MODES: SEVERITY, OCCURRENCE AND DETECTION

a) Failure modes may be grouped based on criteria such as systems or sub-systems.

b) Each failure mode is evaluated in terms of the

1) potential impact (**Severity**)
2) likelihood of it occurring (**Occurrence**)
3) degree of difficulty to detect (**Detection**)

c) This process will produce a Risk Priority Number (RPN) which can be used to prioritize action planning.

TEMPLATE for Failure Mode Effect Analysis (FMEA) tool				
Identify *all* the activities in the process that is being reviewed	For *each* activity identify all the things that could go wrong.	For *each* thing that could go wrong, identify the effects that would arise from the potential failure.	Calculate the SOD# • **Severity** should the event occur • Probability of the **Occurrence** • Ability to **Detect** the event	Risk Priority Number (RPN). Produce plans to minimize the potential for occurrence, or to mitigate should the event occur.
1.				
2.				
3.				

SMART TOOL

(Specific, Measurable, Agreed Upon, Realistic and Time-based)

WHAT IS A SMART TOOL? Once you have planned your project, turn your attention to developing several goals that will enable you to be successful. Goals should be **S M A R T — Specific, Measurable, Agreed Upon, Realistic and Time-based.**

A goal might be to:

1) hold a weekly project meeting with the key participants [Team] and/or
2) organize and run a continuous test program throughout the project.

The acronym S M A R T has a number of slightly different variations, which can be used to provide a more comprehensive definition for goal setting:

S— specific, significant, stretching
SPECIFIC: well defined. Clear to anyone that has a basic knowledge of the project

M— measurable, meaningful, motivational
MEASURABLE: Known if the goal is obtainable and how far away completion is known when it has been achieved

A— agreed upon, attainable, achievable, acceptable, action-oriented
AGREED UPON: Agreement with all the stakeholders what the goals should be

R— realistic, relevant, reasonable, rewarding, results-oriented
REALISTIC: Within the availability of resources, knowledge and time

T— time-based, timely, tangible, trackable
TIME-BASED: Enough time to achieve the goal. Not too much time, which can affect project performance

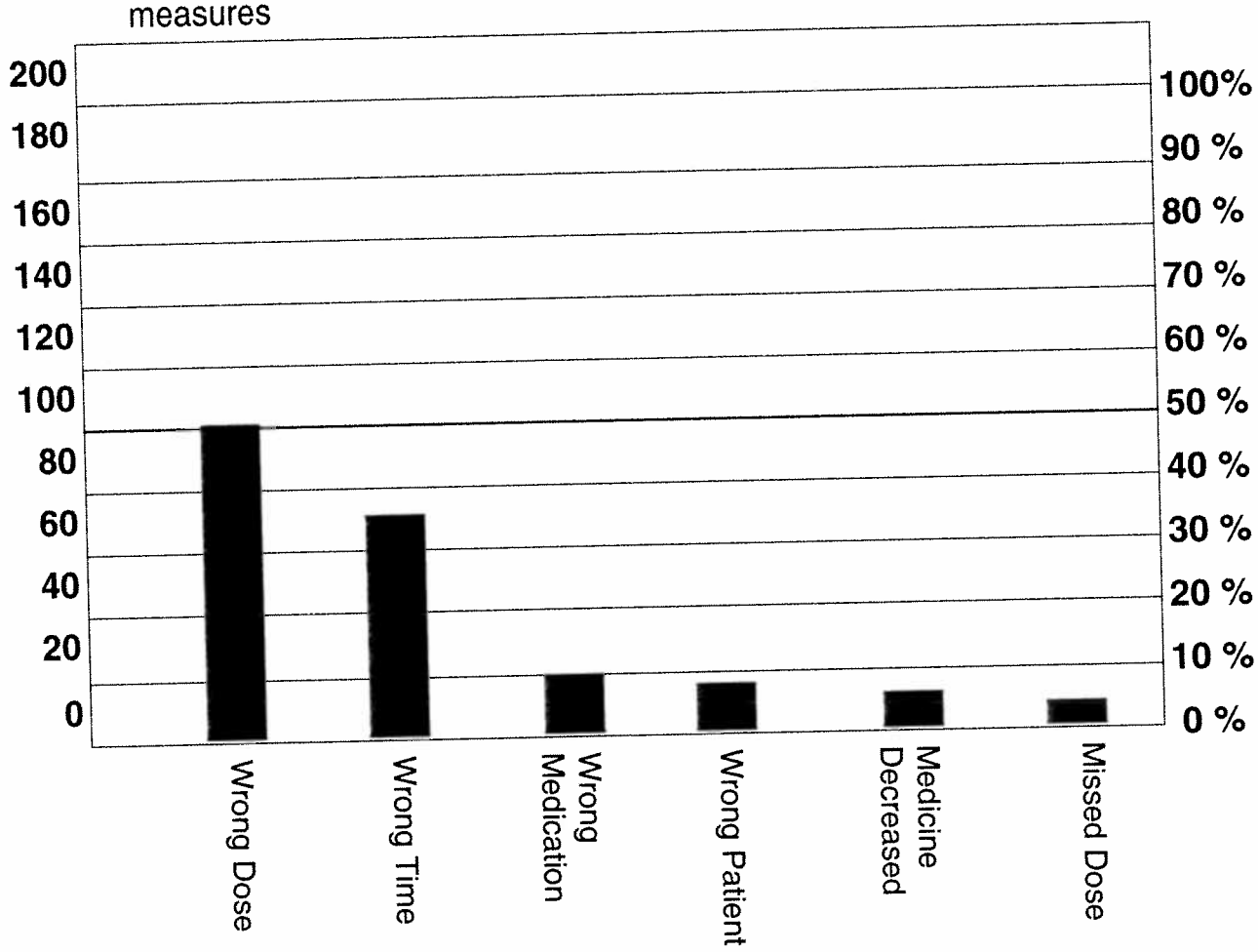
PARETO ANALYSIS CHART

What is a Pareto Chart? A bar graph used to arrange information in such a way that priorities for process improvement can be established.

> Pareto diagrams are named after Vilfredo Pareto, an Italian sociologist and economist, who invented this method of information presentation toward the end of the 19th century. The fundamental idea behind the use of Pareto diagrams for quality improvement is that the first few (as presented on the diagram) contributing causes to a problem usually account for the majority of the result. Thus, targeting these "major causes" for elimination results in the most cost-effective improvement scheme.

Why is it important? Pareto charts provide a tool for visualizing the Pareto principle, which states that a small set of problems (the "vital few") affecting a common outcome tend to occur much more frequently than the remainder (the "useful many"). A Pareto chart can be used to:

1) decide which subset of problems should be solved first
2) decide which problems deserve the most attention
3) provide a before-and-after comparison of the effect of control or quality improvement measures



Steps of PARETO CHART

DEFINITION:

A bar graph used to arrange information in a way that priorities for process improvement can be established.

PURPOSE:

1. To display the relative importance of data.
2. To direct efforts to the biggest improvement opportunity by highlighting the vital few in contrast to the useful many.

HOW TO CONSTRUCT:

1. Determine the categories & units for comparison of the data, such as frequency, cost, or time.
2. Total the raw data in each category, then determine the grand total by adding the totals of each category.
3. Re-order the categories from largest to smallest.
4. Determine the cumulative percent of each category (i.e., the sum of each category plus all categories that precede it in the rank order, divided by the grand total & multiplied by 100).
5. Draw and label the left-hand vertical axis with the unit of comparison, such as frequency, cost or time.
6. Draw and label the horizontal axis with the categories. List from left to right in rank order.
7. Draw and label the right-hand vertical axis from 0 to 100 percent. The 100 percent should line up with the grand total on the left-hand vertical axis.
8. Beginning with the largest category, draw in bars for each category representing the total for that category.
9. Draw a line graph beginning at the right-hand corner of the first bar to represent the cumulative percent for each category as measured on the right-hand axis.
10. Analyze the chart. Usually the top 20% of the categories will comprise roughly 80% of the cumulative total.

Suggestions:

- Create before and after comparisons of Pareto charts to show impact of improvement efforts.
- Construct Pareto charts using different measurement scales, frequency, cost or time.
- Use objective data to perform Pareto analysis rather than team members opinions.
- If there is no clear distinction between the categories - if all bars are roughly the same height or half of the categories are required to account for 60 % of the effect - consider organizing the data in a different manner and repeating Pareto analysis.

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INTERNET SITES OF INTEREST

HCANJ's Pain Management, Falls Management and Medication Management Best Practice publications available for complimentary download at www.hcanj.org. Click on "Best Practice" for related documentation and forms.

Advancing Excellence In America's Nursing Homes	http://www.nhqualitycampaign.org
Agency for Healthcare Research and Quality (AHRQ)	http://www.ahrq.gov
American Geriatrics Society	http://www.americangeriatrics.org
American Health Care Association (AHCA) / National Center for Assisted Living (NCAL)	**http://www.ahcancal.org**
American Medical Association	http://www.ama-assn.org
American Medical Directors Association	http://www.amda.com
American Society of Consultant Pharmacists	http://www.ascp.com
Association for Professionals In Infection Control and Epidemiology	http://www.apic.org
Centers for Disease Control and Prevention (CDC)	http://www.cdc.gov
Centers for Medicare & Medicaid Services (CMS)	http://www.cms.hhs.gov
FirstGov.com, official US site to government agencies	http://www.firstgov.gov
Food and Drug Administration	http://www.fda.gov
Health Care Association of New Jersey (HCANJ)	**http://www.hcanj.org**
Health Care Quality Strategies (NJ QIO)	http://www.njqio.sdps.org
Institute for Health Care Improvement	http://www.ihi.org
Institute for Safe Medication Practices	http://www.ismp.org/
Joint Commission on Accreditation (JCAHO)	http://www.jcaho.org
Journal of American Medical Association (JAMA)	http://www.jama.com
National Center for Health Statistics	http://www.cdc.gov
MyInnerview	http://www.myinnerview.com
National Guideline Clearinghouse	http://www.guideline.gov
National Institute On Aging	http://www.nia.nih.gov
National Quality Measures Clearinghouse	http://www.qualitymeasures.ahrq.gov
NJ Department of Health and Senior Services	http://www.state.nj.us/health
Press Ganey Associates, Inc.	http://www.Pressganey.com
Substance Abuse and Mental Health Services	http://www.samhs.gov
The New England Journal of Medicine	http://www.nejm.org
Technology for Long Term Care	http://www.techforltc.org
US Department of Health and Human Services	http://www.hhs.gov
US Department of Health and Human Services National Institutes of Health	http://www.nih.gov
US National Library of Medicine	http://www.nlm.nih.gov