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Quality Improvement Standards

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Quality Improvement Standards

Facility Quality Assessment and Performance Improvement (QAPI) Program

According to the new ESRD Conditions for Coverage (494.110) "The dialysis facility must develop, implement, maintain and evaluate an effective, data driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team (IDT). The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS". The members of the interdisciplinary team participating in the QAPI activities (QAPI) committee, must, minimally, consist of Physician, Registered Nurse, Masters-prepared Social Worker, and Registered Dietitian. This facility-based team must be led by facility Medical Director, who may also serve as a physician representative of IDT. Within their individual QAPI program, facilities are expected to utilize community-accepted standards/values associated with clinical outcomes, and use CROWN Web** and Dialysis Facility Reports to determine comparison or "average" values associated with clinical outcomes. If a facility has areas of QAPI that do not meet target levels or areas where the facility performance is below average (per data reports), the facility is expected to take action toward improving these outcomes. The important aspects of QAPI program are appropriately monitoring data/information, prioritizing areas for improvement, determining potential root causes, developing, implementing, evaluating, and revising plans that result in improvement in care.

The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes themselves. The program must include, but not limited to, the following:

(V629) Adequacy of dialysis	Kt/V, URR
(V630) Nutritional status	Albumin, body weight
(V631) Mineral Metabolism and Bone disease	PTH, Ca+, Phosphorus
(V632) Anemia management	Hgb, Ferritin
(V633) Vascular access	↑ Fistula, ↓ Catheter Rate
(V634) Medical injuries and medical errors identification	↓ Frequency of specific errors: • Adverse occurrences • Hand hygiene • Patient falls • Incorrect dialyzer or dialyzing solution • Medication omission or errors • Non-adherence to procedures
(V635) Reuse	↓ Adverse outcomes
(V636) Pt satisfaction	↑ Survey scores
(V637) Infection control	↓ Infections, ↑ vaccination status

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QAPI: Tools & Techniques

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QAPI Tools & Techniques

Brainstorming

What it is:
- A Structured group session to generate a list of ideas about an issue in a short period of time.

What it is used for:
- Generating lists of Problems, Topics for Data Collection, Potential Solutions, and Items to Monitor
- Stimulate creativity
- Visualize all aspects of a topic

When it is used:
- Throughout all phases of process improvement as appropriate. Anytime multiple ideas are needed.

Multi-Voting

What it is:
Technique for narrowing down a broad list of ideas to those most important.

What it is used for:
- Used in conjunction with brainstorming to identify the critical few items worthy of immediate attention.

When it is used:
- Can be used throughout all phases of process improvement as appropriate. Used to identify the key ideas of a brainstorming session.

Check sheet

What it is:
- A data recording form that tells how many times something has happened. It provides a clear record of the data that has been gathered. Each check sheet is custom-designed for its purposes.

What it is used for:
- To gather data (facts) based on sample observation in order to begin to detect patterns.
- To measure a process.
- To show visually where something is happening.

When it is used:
- In problem identification and definition, e.g., gather data to get an idea of the scope of a situation.
- Problem analysis

Run Chart (Example: see page II-32 - II-34)

What it is:
- Points plotted on a graph in the order in which they become available over time.

What it is used for:
- To display data and identify trends.
- To identify shifts from the average.
- For process improvement, e.g., if the shift is favorable, it should be a permanent part of the system; if it is unfavorable it should be eliminated.

When it is used:
- To analyze data
- To monitor solutions

Fishbone (Cause and Effect) (Example: see page II-30 & II-34)

What it is:
- A diagram showing a large number of possible causes of a problem, using a main horizontal line defining a problem, with related topics connected to the main line (producing a "fishbone" shape).

What it is used for:
- Getting the big picture of a problem.
- Facilitating a team's use of their personal knowledge to identify causes of a problem.
- Providing ideas for data collection and/or solutions.

When it is used:
- In problem identification and definition.
- In analysis of a problem to determine causes.
- In identifying causes of variation.

Pareto

What it is:
- Pareto charts are based on the Pareto Principle: most effects come from relatively few causes.
- A bar chart that visually represents the distribution of events being studied. The occurrence frequency is represented in descending order from left to right; the most frequent occurrence is on the left and least frequent occurrence is on the right.

What it is used for:
- To categorize and display data using vertical bar graphs.
- Helps to determine the relative importance of problems or conditions.
-

When it is used:
- To choose a starting point for problem solving, to monitor success or identify the greatest contributor to a problem.

Histogram

What it is:
- A graphic summary of variation in a set of data. A pictorial display that enables us to see patterns that are difficult to see in a simple table of numbers.

What it is used for:
- When you need to discover and display the distribution of data by bar graphing the number of units in each category.
- To analyze and interpret the distribution of data.

When it is used:
- For analysis of data and data display. Patterns in the variation from the norm can often tell us a great deal about the cause of a problem.

Flowchart (Algorithm)

What it is:
- A graphic representation of the sequence of steps that are performed in a specific work processes

What it is used for:
- To identify the actual path that a product or service follows to identify redundancies, inefficiencies, and misunderstandings.
- To identify the ideal path for a product or service.
- To create a common understanding of how a work process should be done.

When it is used:
- Problem identification.
- Problem analysis.
- Planning solutions (ideal path)

Example Of QAPI:

Dialysis Access Infection

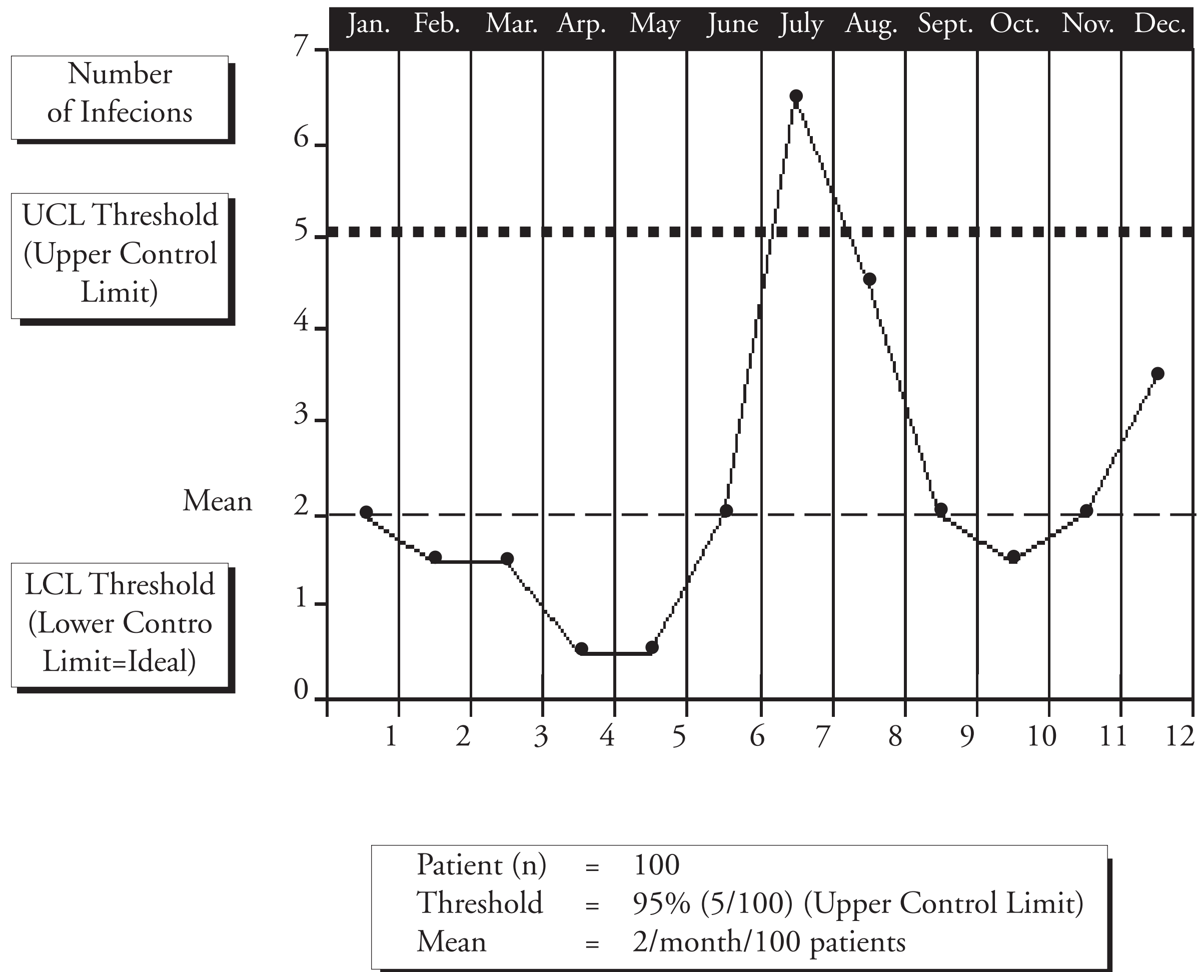
One of the key concepts in the previous list is the "focus on functions and processes". A number of authors have commented on the problems with "inspection" as a method to search for "bad apples". Even if an individual problem is identified, or a particular emergency handled, there are not many current quality control measures that can solve broader problems in the "system" as a whole. More productive goals that have been suggested have been:

a) To study the processes that contribute to care in the facility setting,
b) Measure performance of processes and outcomes.
c) Take action to improve the way processes are designed and carried out.

Examples of process problems include wasting time waiting when it should not be necessary, having to redo work because of some system failure the first time, wasted steps in procedures, duplicated efforts, and loss of information. Management studies in QAPI have shown that these types of failures are more often related to the system than to individuals.
In order to adequately study processes, the use of reliable statistics is also important. Statistical charts don't need to be complicated or incomprehensible to be reliable. In his book Quality Without Tears (1984), Crosby states:

"*The charts are made up with an upper and lower limit representing the 'tolerance' of the process. Each measurement is recorded by a dot on the chart. If a dot is within the lines, keep running. If the dots are heading outside the lines, do something. If the dot is over the line, shut down. That is all there is to it.*"

An example of a "control chart" is listed on the following page. In this particular example, most QI programs doing a quarterly review of infection rates might not review or act upon the rising infection rate until after the number exceeded the "threshold". A QAPI approach, emphasizing ongoing (versus periodic) monitoring, would begin some type of internal review process as the rate began to rise, in this case before the number increased beyond the "upper control limit".



In order to investigate and follow up on problems in a Quality Improvement environment, there must be a cooperative effort by everyone in the facility or organization. This is important, because rather than just "putting out fires" when problems are discovered, QAPI emphasizes evaluation of the system that surrounds the problem as well as investigating direct causes of the problem itself. In the infection rates example, a traditional quality assurance audit-type approach would be for a physician or QI staff member to pull the medical records of the 6 patients with documented infection rates, and try to evaluate what occurred in the individual cases. In QAPI, efforts would go beyond the question of "why did the rate go above threshold for 6 particular patients in July", and include additional questions of "what occurred in June to cause a rise in the rate", "what elements of our entire infection control procedure might have contributed to a rising rate", and "how can we prevent this in the future".

For this type of system-wide evaluation to occur, all staff working in the facility need to feel that quality is their responsibility, not just administration's, and be involved in system review activities. Physicians and administrators must also learn to share responsibility for quality patient care with staff members in order to create a team-oriented environment. The overall philosophy in QAPI is that staff members want to do a good job, and are committed to doing their best. In the previous example,

rather than having just one or two individuals tracking down selected patient record information, a team conference or a “quality improvement team” (selected by the QAPI committee and composed of staff members directly involved in infection-control aspects of patient care) would work together to try to gather answers to the additional system questions raised.

Implementation of QAPI In The Facility Setting

The example below provides a flow chart example of putting a QAPI process into action. As the renal community began to adapt QAPI concepts into practice, more articles and example programs have emerged.

Despite the obvious value of such a system, there are also initial difficulties with implementation. Although quality care ultimately costs less than poor care, training of staff and the paid time away from direct patient care for QAPI team activities will initially cause cost increases. However, such cost increases do not need to be overwhelming or massive. For example, rather than investing large blocks of time in full-scale education programs, a facility can begin introducing staff to the concepts of QAPI by placing selected articles where everyone will have access to them, and discussing QAPI approaches as part of regularly scheduled staff or patient care conferences. Each facility must weigh any cost increases against the real costs of an inferior patient care environment (staff turnover due to frustration and dissatisfaction, patient lawsuits from injuries, patient transfers due to dissatisfaction with care, etc.).

Working Example: Applying the QAPI Approach To Access-Related Infections

A QI committee at a hemodialysis facility decided to look at their infection rates and see if improvements could be made.

Step 1: Examining Past Patterns & Establishing A Norm, Or “Mean”

As a first step, they tallied up the number of access infections during the previous year. They had monitored infections on a quarterly basis before, so they converted the quarterly data into monthly data to look for more specific changes. They then set up a “run chart” showing changes, and then computed a “mean” (based on the total number of infections divided by 12 months). Since the unit had an average of 100 patients per any given month, the QAPI committee decided that a threshold of 95% (no more than 5 infections per 100) would be a reasonable level, and to investigate any infections occurring above that “upper control limit”. There is no “lower control limit” in this case (the opposite level, which may mean taking different action, depending on the problem), since the ideal is to have no infections.

Step 2: Committee Evaluation Of Initial Data

After plotting out and reviewing the patterns of infections of the previous year, the QAPI committee assigned a subcommittee to investigate possible reasons for the infections rates illustrated. The subcommittee was composed of a physician, nurses and technicians from the facility.

Step 3: Construct A "Fishbone" Diagram

This subcommittee met to "brainstorm" all possible reasons why infections might be occurring. The initial process involved having members come up with any type of factor that might contribute to infection rates. Once a list of these was developed, the subcommittee organized these factors into categories: patient, staff, equipment and environment. A "fishbone" (or cause and effect) diagram was constructed, visually showing the categories and factors. The committee then reviewed and investigated each part of the diagram to see which areas were most likely to impact the infection rate.

Step 4: Investigate Possible Contributing Factors

The subcommittee members divided up the investigative workload. For example, one staff member looked at the "environment" portion of the diagram, the storage and patient care areas where the sterile supplies were kept, looking for problems (i.e. unclean environment, roof leakage, temperature fluctuations, etc.) that would compromise the materials used to initiate dialysis. Another staff member looked into the equipment itself (i.e. were the packages outdated or were there holes in outside covering, were there new brands of needles or tubing being used staff might not be familiar with, etc.). Another member looked at the patient records for evidence of physiological factors (e.g. infections elsewhere in the body, compromised immune system) or problems with self-care techniques/personal hygiene that might impact the infection rate. Another staff member investigated staff-related issues, such as if there were new staff in the unit during the "peak" infection rate periods, possible breaches in sterile technique during initiation of dialysis, seasonal staffing patterns, etc.

Step 5: Report Initial Findings To QAPI Committee

After doing an investigation on the four general areas, the subcommittee members went back to the QAPI committee with their initial findings:

Environment: There were no problems found. The storage room and patient care areas were clean and orderly.

Equipment: The packaging of tubing and cannulation devices was found to be intact, with no suspicion of break in sterility. A new type of cannulation device had been ordered in May, and regular staff members had been oriented to its use in small educational sessions during that month. Questions arose during the committee meeting about whether all staff working in the unit involved in initiating dialysis had attended the education sessions.

Staff: Discussion led to the staff working in the unit between May and September. Staffing patterns during that time frame showed a seasonal drop in the number of regular full-time staff members due to summer vacation, as well as a slight increase in the number of patients. During the time regular staff members were off, temporary replacement staff had been utilized to fill the staffing gaps. Further discussion hypothesized that most replacement staff, which were not present in May, had not attended the educational sessions. Depending on their level of experience, they also may not have been familiar with the unit's new cannulation device.

Patient: Based on the medical record reviews, the patients with infections had no common denominator, other than developing their site infections within the same time frame. No patient hygiene issues appeared to be contributory, but two of the six patients were HIV+, which led the committee to suspect possible immune system problems that made them more susceptible.

Step 6: QI Committee To Recommend A Plan Of Action

After systematically reviewing all of the areas of the fish-bone diagram, the committee concluded that there were a series of problems that need to be addressed for future prevention of access site infections.

1. The combination of new equipment and some temporary staffing changes were felt to be the largest contributing factors to the sudden increase in access site infections. The committee also noticed that at the end of the previous year (November & December) another upward trend of infections occurred again, possibly related to holiday time off and/or illness.

    a. Since the seasonal staffing patterns were expected to be an ongoing condition, the QI committee recommended expanding orientation time for new or replacement staff, to include specific review of the new cannulation system. The committee also recommended that this orientation include observation of the new staff member's cannulation technique.

    b. Another suggestion was to translate a one-page section of the manufacturer's instruction booklet (reviewing the specific cannulation technique) into at least one other language, to have available in the unit as a "quick reference". The committee felt this would be helpful for new or temporary staff, if a regular staff member or supervisor was not available to interpret or answer questions.

2. Although the reasons for the individual patient infection rates varied, there were patients identified with diminished immune responses. As a preventive measure, the QAPI committee decided to hold an "in-service" review of aseptic technique in cannulation periodically for all staff members.

Step 7: Future Follow-up

To monitor infection rates in the future, the QAPI committee decided on several steps:

a. To continue tracking infections on a monthly instead of a quarterly basis. They felt this information gave them more specific changes, and a time frame in which to act more swiftly should the trend turn upward.

b. To continue to include aseptic technique as part of new staff orientation, and have review programs for staff on aseptic technique at least once per year.

Data Sources for QAPI & QAPI
(Quality Assessment & Performance Improvement Projects)

- Medical Records
- Dialysis Record Sheets
- Patient Care Plans
- Hospitalization Records
- Laboratory and Other Diagnostic Records
- Incident Reports
- Adverse Occurrence Reports
- Water Quality Monitoring Reports
- Culture Reports: Water, Reuse, Dialysate
- Hepatitis Surveillance Reports
- Reuse Master File
- Patient Satisfaction Surveys
- State and Federal Surveys
- Medical Device Alerts
- Manufacturer Recalls
- Performance Appraisals
- Utilization Review Reports
- Transplant tracking log

Source: Douglas Vlchek et al, Quality Assurance Guidelines for Hemodialysis, 1991

Additional Sources for QAPI:

- CMS Clinical Performance Measures (CPM) Reports Data: www.cms.gov/cpmproject/

- ESRD Network 18 Annual Report: www.esrdnetwork18.org

- United States Renal Data system annual report: www.usrds.org

- Kidney Disease Outcomes Quality Initiative (K/DOQI): www.kidney.org/professionals/kdoqi

- Centers for Disease Control (CDC) annual surveillance of dialysis-associated diseases report: www.cdc.gov/ncidod/osr/index

Examples Of QAPI Indicators Of Care For ESRD

1. Infection Control
   Indicators:
   A. Access-related infections
   B. Development of hepatitis (or seroconversion)
   C. Pyrogenic reactions or dialysis-related septicemia
   D. Peritonitis
   E. Post-transplant infections

2. Mortality
   Indicators:
   A. Treatment-related complications contributing to deaths
   B. Deaths during dialysis treatment (dialysis-related)
   C. Deaths within three (3) months of transplantation (transplantation-related)
   D. Undiagnosed or preventable deaths

3. Hospital Admissions
   Indicators:
   A. Documentation of all ESRD or dialysis-related hospitalizations
   B. Documented total ESRD admissions and length of stay (# hospital days per patient year)

4. Adverse Patient Occurrences (APO)
   Indicators:
   A. Evidence of regular review of patient records to screen for undocumented APOs.
   B. Report of five (5) or less APOs per 100 patient treatments

5. Patient And Staff Satisfaction
   Indicators:
   A. Documentation that all pts/staff receive an evaluation form during evaluation period
   B. Overall satisfaction ratings are 75% or above
   C. At least 50% of staff and patients in unit surveyed

6. Vocational Rehabilitation
   Indicators:
   A. Documentation of rehabilitation potential on all Multidisclipnary Comprehensive Patient Assessments
   B. Evidence that patients eligible for vocational rehabilitation are being referred

7. Incidents
   Indicators:
   A. Evidence of ongoing monitoring of incident reporting at QI committee, and follow up with Risk Management committee (as needed)

B. Report of no more than three (3) incidents per 100 treatments administered
C. No individual staff member will be responsible for more than three (3) incidents per month

8. Water Treatment
Indicators:
A. See state and AAMI standards for water treatment/culture procedures

9. Reuse
Indicators:
A. Reports of no more than three (3) incidents or APOs related to reuse per 100 treatments with a reprocessed dialyzet.
B. Evidence of data collection on number of patients reusing, and average number of reuses attained.
C. Detailed indicators developed from national standards (e.g. CMS)

10. Equipment Maintenance
Indicators:
A. Records of routine maintenance/repair and safety testing for ALL equipment used in-patient care setting
B. Records of emergency equipment (like crash carts) show evidence of routine inspection, timely rotation of supplies and current expiration dates

11. Medical Records
Indicators:
A. Documentation on medical records by all members of team (MD, nurse, social service, dietitian, etc.) demonstrating alterations in-patient care plan (specify frequency of notations by each specialty)
B. Documentation of involvement of family/significant others in planning process
C. All records have minimum compliance of 85% in any area audited; records not meeting minimum are subject to focused review

12.Credentials
Indicators:
A. Physicians, nurses, social workers have current licenses, malpractice insurance, professional certification, and evidence of continuing education activities on file
B. Technicians have professional certification on file
C. All staff involved in patient care have current CPR and fire safety certification
D. All staff at facility have access to appropriate Continuing Education activities

13. Nursing Standards
Quality Assessment & Performance Improvement should also include monthly monitoring of selected nursing standards/aspects of care and indicators on a facility level. The following standards are adapted from ANNA's "Standards and Guidelines of Clinical Practice for Nephrology Nursing", 1999:

A. Universal Nephrology Nurse Guidelines for Care (Common to All Renal Disease Treatment Modalities):
   1. Anemia
   2. Nutrition & metabolic control
   3. Fluid management
   4. Bowel function
   5. Urine output
   6. Skin integrity
   7. Infection
   8. Hepatitis prevention & management
   9. Tuberculosis prevention
   10. Congestive heart failure
   11. Sleep
   12. Activity & rehabilitation
   13. Sexuality (adult & adolescent)
   14. Self-concept
   15. Coping
   16. Family process
   17. Selection of renal replacement therapy
   18. Discontinuation of renal replacement therapy

B. Standards for Hemodialysis and PD:
   1. Pre-dialysis assessment
   2. Patient education
   3. Equipment assessment
   4. Intradialytic monitoring
   5. Initiation of treatment
   6. Termination of treatment
   7. Post-treatment assessment
   8. Adequacy of dialysis

C. Standards for Hemodialysis:
   1. Vascular access
   2. Anticoagulation
   3. Renal Osteodystrophy
   4. Hyperkalemia
   5. Fluid imbalance (treatment-induced)
   6. Hemolysis
   7. Pyrogenic reaction
   8. Air embolus
   9. Disequilibrium

D. Standards for Peritoneal Dialysis:
   1. Pre- and Post-op care
   2. Catheter integrity

3. Catheter exit site or tunnel infection
4. Peritonitis
5. Catheter site exit leak
6. Inadequate dialysis inflow/outflow
7. Bloody peritoneal effluent
8. Back or shoulder pain
9. Abdominal pain
10. Hyperglycemia
11. Protein loss

E. Standards for Transplantation:
   1. Pre-Op patient & donor education
   2. Physiological maintenance (cadaveric donor only)
   3. Evaluation of potential donor or pre-transplant evaluation of recipient
   4. Work-up studies
   5. Post-Op care:
      a. Pulmonary
      b. Fluid management
      c. Nutrition/medication education
      d. Bowel function
      e. Urinary function
      f. Care of operative site
      g. Post-op comfort management
      h. Allograft dysfunction
   6. Discharge plan

14. Patient Record Review Standards/Indicators

For Medical Review Board medical records standards and clinical indicator "goals", refer to Section III of this manual.

Examples of QAPI Ideas for Pediatric ESRD Dialysis Units

- Machine PM's
- Machine cultures
- Machine availability issues (timely repairs)
- Water quality (AAMI)
- Water cultures
- Dialysate cultures
- Ototoxic drug alerts
- Diet issues
- Dialysis Adequacy
- Pre-chronic ESRD education
- Preservation of vascular access (avoid BP's, phlebotomy, etc.)
- General Education issues (school, home school, tutor, etc.)
- Play & recreational opportunities
- Pediatric to adult unit transfer preparation
- Albumin
- Anemia management
- Bone disease
- Blood pressure
- Vascular access (more fistulas, less catheters, stenosis monitoring)
- Acute to chronic issues (sharing information, education, scheduling, discharge planning, chronic unit placement, PT evaluation if needed, transportation arrangements, Psych evaluation if needed, permanent access planning, etc.)
- Nurse staffing/on-call issues
- Family, significant other issues
- Exercise
- Health maintenance & promotion
- Depression, quality of life, withdrawal from dialysis assessment
- Vascular access infection prevention & tracking
- Physician dialysis order compliance
- Expiration dates & labeling of medications (crash cart, drawers, refrigerator, etc.)
- Patient grievances (prevention/ trending)
- Hospitalization trends
- Safety (physical plant, preventing injury & error)
- Referral for transplantation

QAPI ideas for Pediatrics Adopted from: Heartland Kidney Network,
ESRD Network 12 Quality Improvement 9/2006

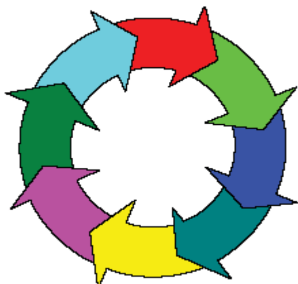
Sample QI Calendar

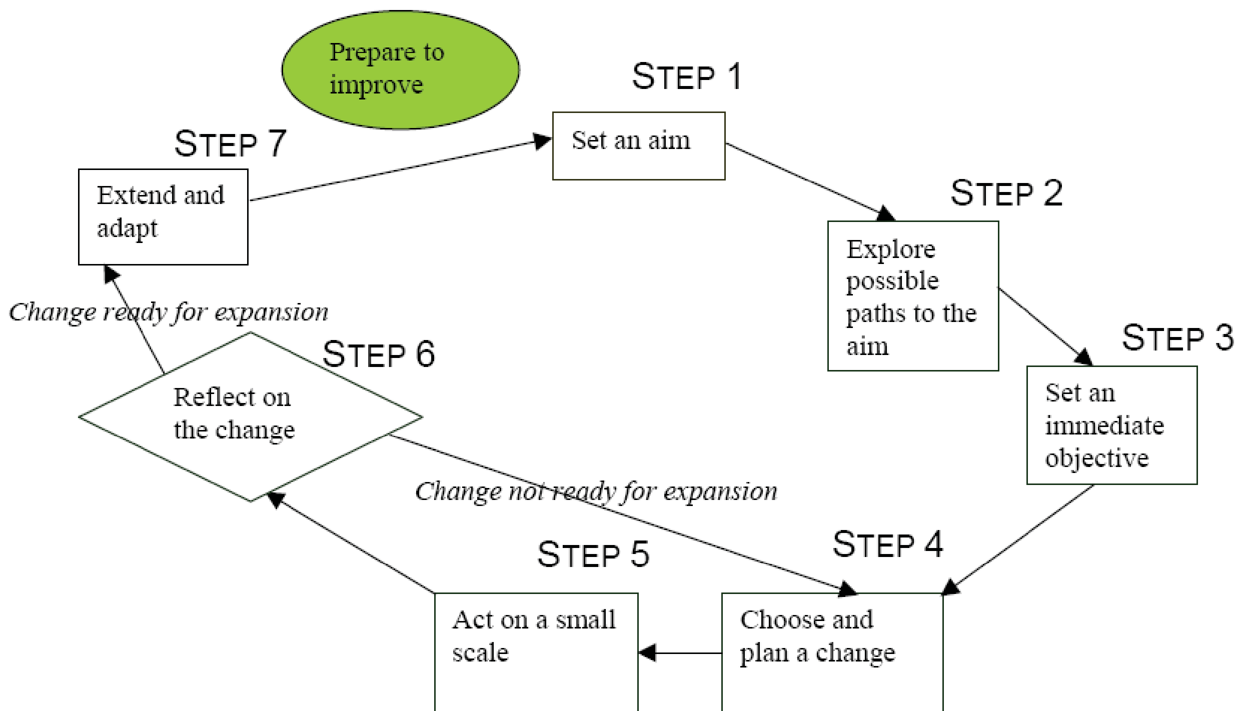
Aspect of Care	Jan	Feb	Mar	April	May	June	July	Aug	Sep	Oct	Nov	Dec
Mortality	X	X	X	X	X	X	X	X	X	X	X	X
Incidents	X	X	X	X	X	X	X	X	X	X	X	X
Water Treatment	X	X	X	X	X	X	X	X	X	X	X	X
Medical Records	X	X	X	X	X	X	X	X	X	X	X	X
Nursing Standards	X	X	X	X	X	X	X	X	X	X	X	X
Infection Control	X			X			X			X		
Hospital Admissions		X			X			X			X	
Adverse Occurrences		X			X			X			X	
Reuse		X			X			X			X	
Equipment Maintenance		X			X			X			X	
"Current QAPI Project"	X	X	X	X	X	X	X	X	X	X	X	X
Patient Satisfaction								X				
Staff Satisfaction							X					
Rehabilitation								X				
Staff Credentials							X					

SUPPORT TRANSFORMATIONAL CHANGE BY PROVIDING THE RIGHT CARE FOR EVERY PERSON EVERY TIME

HOSPITAL QUALITY INITIATIVE

MULTI-TOPIC COLLABORATIVE:
Rapid Cycle Improvement Process Information





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RAPID CYCLE IMPROVEMENT
Rationale

Today's society functions at a pace that would never have been believed by our forefathers. The need to see improvement in quality of care is being put under the same pressurized plan for time and change. Healthcare Quality Strategies, Inc., (HQSI) is committed to working with healthcare professionals to help them respond to these challenges using the most up-to-date quality improvement methods, including techniques required for **rapid cycle quality improvement**. Rapid cycle plans are not just to do things faster, but to do things better.

Historically, quality improvement teams were convened, received available quality data and planned future activities that often included collecting data from a large number of medical records. These activities frequently required multiple meetings over many weeks or months. Unfortunately, all this activity often led to little change in clinical care processes. As a result, team members would often grow disinterested and withdraw from the quality improvement effort. Even when interventions were developed, they were often ineffective in making improvements.

Disadvantage of traditional quality improvement methods

- Usually collect large numbers of records (monthly or quarterly) before planning a change
- Data from long periods of time may make it more difficult to effectively determine what intervention actually caused the change
- Testing ideas for change take a long time
- If tested intervention is unsuccessful, quality improvement has been delayed

Advantages of rapid cycle improvement using small sample size

- Can test pilot ideas quickly
- Can test ideas for change side by side with existing process
- Can test many ideas
- Provides opportunity for "failures" without impacting performance
- Minimizes resistance upon implementation of successful changes

Where do we start?

Three fundamental questions must be asked:

- What are we trying to accomplish?
- How will we know that a change is an improvement?
- What changes can we make that will result in improvement?

What are we trying to accomplish?

When we begin to examine the question regarding what are we to accomplish, a team must understand the need to set a clear aim or goal by developing an aim statement. A specific goal must be set at the beginning and it must have a numerical measure. All team members should understand this goal. Groups can be working together thinking they share common objectives only to discover later that many had not shared some assumptions with the group. Working through these assumptions at the beginning is a must. This will assist the team when other side issues are being addressed and focus begins to wander from the true goal. Reminding the team of the aim statement will bring the group back on track.

How will we know that a change is an improvement?

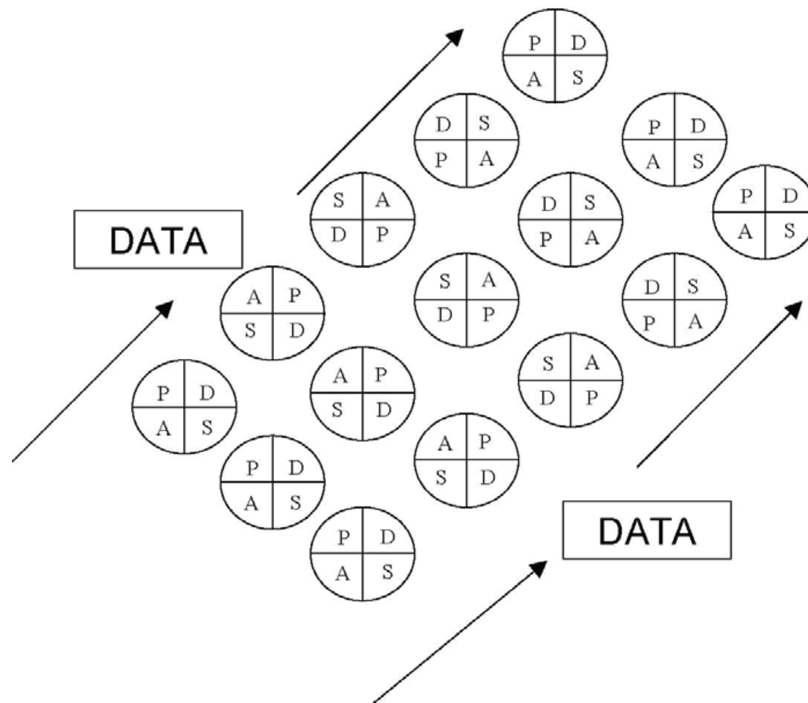
The measurement of data is the only way to ensure that changes put into place are actually improvements. Teams should consider the following points when collecting data:

- Do not wait for formal baseline data. Measure where you are now. This is not the time to have people become defensive over data. It is common for people in this stage to challenge data instead of focusing on quality improvement efforts
- Remember the reason a team is working on a project is to improve care, not to set up a perfect measurement system
- Collect useful data, not perfect data. The purpose of the data is to learn, not to evaluate. Keep it simple
- Use small sampling as part of the plan to collect the data. Why measure every case when a few records will give you what you need
- Train those asked to collect data and give them understandable instructions
- Encourage those that collect data to share physician practice patterns that are noted during the abstraction of data
- Plot data over time on a run chart

What changes can we make that will result in improvement?

- Team members should identify and apply specific changes that have been used in other settings.
  Steal shamelessly!
- Team members should identify and test specific changes that other organizations have found effective. One example is the idea of reducing the time for administration of antibiotics. Many hospitals now have the recommended antibiotics for patients with pneumonia stored in the Emergency Department. Similarly, operating room staff may consider the idea of keeping recommended antibiotics for prophylactic use in the surgical suite. This can speed up the change process, but will still allow teams to include ideas developed by their own members.

- Use multiple cycles of improvement. Teams are usually familiar with the Deming Cycle of Plan/Do/Check/Act now referred to as Plan/Do/Study/Act. This cycle is used in quick, rapid successions. After a change is made, data is collected on a small sample to see if it worked. If not determine why. The change is then adapted, abandoned or adopted, and then another is tested. Multiple small changes are often more effective than trying to make a major improvement with a single change.



- Have those key stakeholders in the process review the proposed change and comment on its feasibility
- Consider using multiple versions of the same process that are tailor made to fit the needs of different areas in the facility. For example, nurses may draw blood cultures in an Emergency Department, whereas on a general nursing floor, lab technicians may perform this function
- Small changes should be encouraged. Start with a frame of mind that begins with “what can we change by Wednesday?” Teams can stalemate waiting for the perfect plan or “the grand fix it all” idea. Grand fixes are often developed by a select few and then are given to others that it affects and who must carry it out. Small changes are more likely to be attempted if they can be reversed when or if it does not work out
- Help stakeholders see themselves as part of the same system working towards the same goal

Change is something that is usually resisted by most. This paradigm shift is no different. Be willing to be a pioneer in change.

Implenting QAPI At The Facility Level
Using The FOCUS-PDSA Model

Based on methodology from the HQAPIP National Anemia Cooperative Study, the "FOCUS-PDCA" approach is used to help implement QAPI on a facility level in ESRD Network 18.

Using the **FOCUS-PDSA** acronym, a brief step-by-step description of the process is provided below. A detailed QAPI example is already available in this manual along with detailed descriptions of the different types of QAPI tools (Section 5).

Step 1 – (Find a Process to Improve):

- Identify the condition or procedure for investigation
- Discuss goals - What are we trying to accomplish? What outcomes do we want?

Step 2 – (Organize a Team That Knows the Process):

- Assemble a team of people involved in the area under investigation; identify leader coordinator
- Assess organizational resources available for quality measurement activities
- Begin documentation procedures (use "storyboard" format)

Step 3 – (Clarify Current Knowledge of the Process):

- Review data collected so far (that shows there may be a problem; "how are we doing?") Keep in mind any limitations the data may have.
- Plan to collect a current data sample - what minimum elements of data need to be collected to give us an overall "snapshot" view of the area of improvement? Don't collect more data than you need for an initial overview. Remember - clinical indicators related to outcome are important quality measures. Compare information to established indicators (e.g., Clinical Performance Measures (CPM) results), K-DOQI guidelines, Lab Data Collection (LDC) results, etc.
- Choose measurement instruments that will provide the basis for data collection (e.g. check sheets) for either chart review or direct observation. Can use prior existing forms or make up new ones. Collect enough data so you can see a basic pattern – (e.g., if a monthly lab measure is collected, get data for at least three months), and if the measure is a quarterly one (e.g. iron), get data for at least 2 or 3 quarters.
- Review data, and set up a run chart (this will form the basis for ongoing tracking of this measure). For example, if hemoglobins (HGB) are collected on all facility patients for a 3-month period, then compute the means of all HGB (total figure divided by # of patients) for each month, and place on a run chart. Another tool that can help look at distribution of data is a histogram - for example, if the mean for a certain set of data (e.g. HGB) is 11, you may also want to look at what percentages of patients fall below or above that mean. Specifically, even if the mean is above a selected minimum (lower control limit) of 10.9, if more than 50% of the patients fall below that mean, there is still a big opportunity to improve the HGB levels for a number of patients in that facility.

- Another way to look at facility performance is to look at the process itself (e.g. treatment of anemia in the facility). Review the process and construct a flowchart. By reviewing exactly how things are done in a step-by-step manner, the team can identify potential problem areas that would not usually be considered. (Suggestion: use CMS's treatment algorithms as comparisons.)

Step 4 – (Understand Source of Process Variation):

- After reviewing baseline data, use the technique of brainstorming to gather ideas from the team of why the results may be occurring. Initially, look at all possible causes of influencing factors related to the process being reviewed.
- By using the multi-voting technique, you can then organize those thoughts into a more organized framework (separate subtopics), and construct a cause & effect (fishbone) diagram. If one segment of the fishbone diagram still seems very complex, do another fishbone diagram of that section.
- Further investigate the most likely factors affecting the results - why does your data not meet the goals/standards set by the team? What is causing the "variation" from the norm? Teams need to look for two primary causes of variation - "common cause" variation, which is a result of problems within the system itself (not always immediately apparent, but correctable - e.g. problems with a reuse procedure resulting in more frequent clotting of dialyzers); and "special" cause variation, which is not a normal part of the system, but can produce significant problems (e.g. an outbreak of Hepatitis B).
- After focusing on the most likely factors causing variation in the process, collect additional data to see what is influencing those factors. For example, if there is an outlier that shows a variation in pattern for the measurement, collect additional data (based on the fishbone diagram) just on those patients (not all patients).
- Review the new data to see which parts of the process are actually being most affected. A Pareto chart (bar graph) is a good way to visually see results in a prioritized format (which is the most frequent variable, in order to occurrence?).
- Continue to analyze results and seek "root" causes of the process under study.

Step 5 – (Select the Process Improvement):

- Review results of analysis (suspected root causes of the variation), and have the team look at the question; what can be changed that will improve the outcome?
- Weight alternatives, and make choices for areas to do an improvement trial. If more than one, select the most important area to intervene in first.

Step 6 – (Plan an Improvement Trial):

- Design an improvement pilot project - "who" will be involved, "what" the intervention(s) will be and tools used to collect data, and the "when" (time frame).
- For defining what data to collect, answer the question, "how will we know that a change is an improvement?" (Look at CMS intervention algorithms as examples.)

Step 7 – (Do Implement a Solution on a Trial Basis):

- Test out the proposed intervention/solution(s) (from Steps 5 & 6) as a pilot program.

Step 8 – (Check/Study Results through Data Collection and Evaluation):

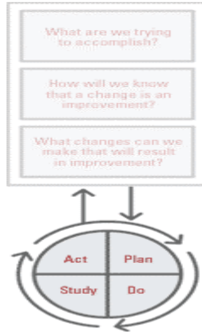
- Did the intervention/solution work? Why or why not?
- Can use the same analysis techniques (e.g. brainstorming) as before?

Step 9 – (Act to Implement the Solution System or Unit-Wide):

- If intervention/solution(s) successful, make plans to integrate them as part of everyday practice (permanent change to the system/process).
- Finish documentation on "storyboard" report form.
- Continue to monitor the baseline data (run chart) to keep track of outcomes in the future (look for patterns showing variation from the norm before significant deviation occurs).
- If results/outcomes were not as expected, go back and look further at either analyzing root causes (Step 4), selecting different areas of the process to improve (Step 5), or making new plans for an improvement pilot (Step 6).

Quality Assessment & Performance Improvement (QAPI) Plan

Cycle (Dates of the project): ______using PDSA Model________________



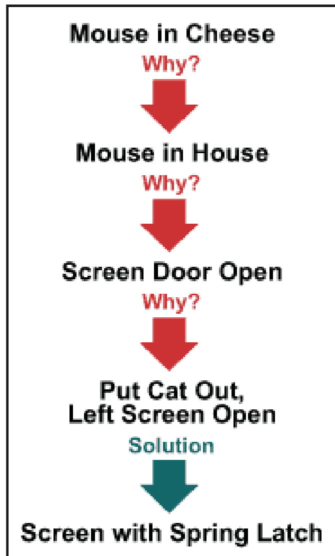
PROJECT:
TEAM:
BACK GROUND:

Step 1. **PLAN:** Plan the test.	What is the objective of this improvement cycle?
	What is the goal? (Include a numeric goal to achieve.)
	Develop a plan to achieve the goal?
	What data sources are needed for the test?
	What measures are used to analyze if you are achieving the goal?
	Monitoring frequency.
Step 2. **DO:** Try out the test on a small scale.	Implement the plan. Document problems and unexpected observations.
Step 3. **STUDY:** Set aside time to analyze the data and study the results.	Analyze the results and compare the results with your goal.
Step 4. **ACT:** Determine if the test was successful or the plan needs to be revised.	If the test was successful, how will you implement the plan on a wider scale?
	If it was not successful, what needs to be changed based on what you have learned? Should you continue to search for other root causes?

Guidelines For Using The PDSA Process To Create Change

PROCESS	Questions To Be Answered	Generate Ideas	Gain Consensus	What To Do Before Proceeding To The Next Step
PLAN: Identify an opportunity and plan for change.	How can we get to where we want to be? What do we do first?What's the best way to do it?	Ideas on how to solve the problem; how to implement solutions; how to monitor and evaluate the trial improvement.	Agree on a design and implementation plan for a trial improvement; agree on criteria for evaluating trial.	Brainstorm possible improvements; analyze strengths and weaknesses; establish criteria for selection; establish time lines and a plan for monitoring and evaluating the trial; update run charts and progress reports.
DO: Implement the change on a small scale.				Document problems and unexpected observations.
STUDY: Use data to analyze the results for the change and determine whether it made a difference.	Have we implemented the trial improvement correctly?Have we followed the monitoring plan?Are we improving?What are we learning?		Agree on effectiveness of trial.	Evaluate improvement trial using established criteria; compare results with desired state; check for new problems; decide to implement change system-wide, or return to root cause analysis (fishbone diagram) to search for other sources of variation; update run chart and progress report.
ACT: If the change was successful, implement the plan and continuously monitor results. If the change did not work, start the process again.	Should we implement system-wide change?Does management support the change?If not, should we continue to search for other root causes?	Ideas for planning system-wide change. (Implement action based on what you learned in the study step. If the change did not work, go through the process again with a different plan using what you have learned in the study step.)	Agree to a new plan for system-wide change; or, return to root cause analysis and start the process again.	Prepare to report results of the project; communicate results throughout the organization; continue to monitor.

Root Cause Analysis (Definition)



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. By directing corrective measures at root causes, it is hoped that the likelihood of problem recurrence will be minimized. However, it is recognized that complete prevention of recurrence by a single intervention is not always possible. Thus, RCA is often considered to be an iterative process, and is frequently viewed as a tool of continuous improvement. Root cause analysis is not a single, sharply defined methodology; there are many different tools, processes, and philosophies of RCA in existence. However, most of these can be classed into five, very-broadly defined "schools" that are named here by their basic fields of origin: safety-based, production-based, process-based, failure-based, and systems-based.

- Safety-based RCA descends from the fields of accident analysis and occupational safety and health.
- Production-based RCA has its origins in the field of quality control for industrial manufacturing.
- Process-based RCA is basically a follow-on to production-based RCA, but with a scope that has been expanded to include business processes.
- Failure-based RCA is rooted in the practice of failure analysis as employed in engineering and maintenance.
- Systems-based RCA has emerged as an amalgamation of the preceding schools, along with ideas taken from fields such as change management, risk management, and systems analysis.

Despite the seeming disparity in purpose and definition among the various schools of root cause analysis, there are some general principles that could be considered as universal. Similarly, it is possible to define a general process for performing RCA.

Wikipedia contributors. Root cause analysis. Wikipedia, The Free Encyclopedia. June 6, 2008, 00:40 UTC. Available at: http://en.wikipedia.org/w/index.php?title=Root_cause_analysis&oldid=217434991. Accessed June 11, 2008.

Another example of RCA overview prepared by the National Aeronautics and Space Administration (NASA) could be found at http://www.hq.nasa.gov/office/codeq/rca/rootcauseppt.pdf

Root Cause Analysis Primer

If I have an unwanted situation which consumes resources and tends to happen in a repeated fashion then there is a possibility that it might be beneficial to figure out what is really causing this situation to occur and remove it so the situation does not occur again. This is generally referred to as Root Cause Analysis, finding the real cause of the problem and dealing with it rather than simply continuing to deal with the symptoms.

This raises several questions:
- How does one determine which situations are candidates for root cause analysis?
- How does one figure out what the root cause is?
- Does the removal of the cause entail less resource expenditure than it takes to continue to deal with the symptom?

Determining Candidates:
In normal chaotic organizational environments it is often quite difficult to find candidates for root cause analysis because the situations which repeat are either distributed over time so one doesn't realize they are actually recurring, or the situation happens to different people so there isn't an awareness of the recurring nature of the situation. When an organization is using an automated problem resolution support system, such as Solution-Builder, it is very easy to determine which situations are recurring with what frequency. Every time a solution is used its frequency counter gets updated, so all one has to do is run reports against the system to determine which solutions are being used with what frequency. Those situations which are recurring with the greatest frequency and consume the greatest amount of resource to rectify are the candidates for root cause analysis.

Finding the Root Cause:
Most situations which arise within an organizational context have multiple approaches to resolution. These different approaches generally require different levels of resource expenditure to execute. And, due to the immediacy which exists in most organizational situations there is a tendency to opt for the solution which is the most expedient in terms of dealing with the situation. In doing this the tendency is generally to treat the symptom rather than the underlying fundamental problem that is actually responsible for the situation occurring. Yet, in taking the most expeditious approach and dealing with the symptom, rather than the cause, what is generally ensured is that the situation will, in time, return and need to be dealt with again.

Consider the specific example of expediting customer orders in an order fulfillment process. The organization has a well defined process for accepting, processing, and shipping customer orders. When a customer calls and complains about not getting their order the most normal response is to expedite. This means that someone personally tracks down this customer's order, assigns it a #1 priority, and ensures it gets shipped ahead of everything else. What isn't realized, until sometime later on, if at all, is that in expediting this order one or more other orders were delayed because the process was disrupted to get this customer's order out the door. What is all comes down to is that expediting orders simply ensures that more orders will have to be expedited later. In systems terms this is a typical "Fixes that Fail" structure which evolves into an "Addiction" structure where the organization becomes addicted

to expediting to deal with customer order complaints.

The appropriate response to this situation is to figure out why the order was in need of expediting in the first place. Yet this is seldom done because the task assigned to the expediter was, "get the order shipped!" and that's as far as the thought processes and investigation are apt to go.

To find root causes there is one really only one question that's relevant, "What can we learn from this situation?" Research has repeatedly proven that unwanted situations within organizations are about 95% related to process problems and only 5% related to personnel problems. Yet, most organizations spend far more time looking for culprits than causes and because of this misdirected effort seldom really gain the benefit they could gain from understanding the foundation of the unwanted situation. Consider the following two scenarios.

Scenario # 1:
The Plant Manager walked into the plant and found oil on the floor. He called the Foreman over and told him to have maintenance clean up the oil. The next day while the Plant Manager was in the same area of the plant he found oil on the floor again and he subsequently raked the Foreman over the coals for not following his directions from the day before. His parting words were to either get the oil cleaned up or he'd find someone that would.

Scenario # 2:
The Plant Manager walked into the plant and found oil on the floor. He called the Foreman over and asked him why there was oil on the floor. The Foreman indicated that it was due to a leaky gasket in the pipe joint above. The Plant Manager then asked when the gasket had been replaced and the Foreman responded that Maintenance had installed 4 gaskets over the past few weeks and they each one seemed to leak. The Foreman also indicated that Maintenance had been talking to Purchasing about the gaskets because it seemed they were all bad. The Plant Manager then went to talk with Purchasing about the situation with the gaskets. The Purchasing Manager indicated that they had in fact received a bad batch of gaskets from the supplier. The Purchasing Manager also indicated that they had been trying for the past 2 months to try to get the supplier to make good on the last order of 5,000 gaskets that all seemed to be bad. The Plant Manager then asked the Purchasing Manager why they had purchased from this supplier if they were so disreputable and the Purchasing Manager said because they were the lowest bidder when quotes were received from various suppliers. The Plant Manager then asked the Purchasing Manager why they went with the lowest bidder and he indicated that was the direction he had received from the VP of Finance. The Plant Manager then went to talk to the VP of Finance about the situation. When the Plant Manager asked the VP of Finance why Purchasing had been directed to always take the lowest bidder the VP of Finance said, "Because you indicated that we had to be as cost conscious as possible!" and purchasing from the lowest bidder saves us lots of money. The Plant Manger was horrified when he realized that he was the reason there was oil on the plant floor. Bingo!
You may find scenario # 2 somewhat funny, and laugh at the situation. It would be better if the situation made you weep because it is often all so true in numerous variations on the same theme. Everyone in the organization doing their best to do the right things, and everything ends up screwed up. The root cause of this whole situation is local optimization with no global thought involved. Scenario # 2 also provides an good example of how one should proceed to do root cause analysis. Once

simply has to continue to ask "Why?" until the pattern completes and the cause of the difficulty in the situation becomes rather obvious.

To Resolve or Not To Resolve:
Once the root cause is determined then it has to be determined whether it costs more to remove the root cause or simply continue to treat the symptoms. This is often not an easy determination. Even though it may be relatively easy to estimate the cost to remove the root cause it is generally very difficult to assess the cost of treating the symptom. This difficulty arises because the cost of the symptom is generally wrapped up in some number of customer and employee satisfaction factors in addition to the resource costs associated with just treating the symptom.

Consider a situation where it is determined that it will cost $100,000 to remove the root cause of a problem and only 5 minutes for someone to resolve the situation when the customer calls with the problem. Initially one might perceive that the cost of removing the root cause is far larger than the cost of treating the symptom. Yet suppose that this symptom is such that when it arises it so infuriates the customer that they swear they will never buy another product from you, and will go out of there way for the next year to tell everyone they meet what a terrible company you are to do business with. How do you estimate to lost business cost associated with this situation. And if you think this is a bizarre case, it is not, for I was personally on an "I hate Midas Muffler" campaign for over two years because they screwed up the brakes on my car. In that two years I managed to reach several thousand people because I preached "I hate Midas Muffler" in my TQM classes, and continued to use them as an excellent bad example.

Postscript:
Is "Root Cause Analysis" really an appropriate phrase? In this apparently endlessly interconnected world, everything seems to influence so many other things. Seeking the "Root Cause" is an endless exercise because no matter how deep you go there's always at least one more cause you can look for. Might "Actionable Cause Analysis" be more appropriate? I think I'm looking for a cause that I can act on that will provide long term relief from the symptoms, without causing more problems that I have to deal with tomorrow.

Additional Resources:
- Archetypes for Organisational Safety - Karen Marais and Nancy G. Leveson
- Bill Wilson's Root Cause Analysis Site
- Maintenance World Root Cause Analysis Articles
- REASON® Root Cause Analysis

theWay of Systems * Feedback * Musings
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Fishbone Diagram

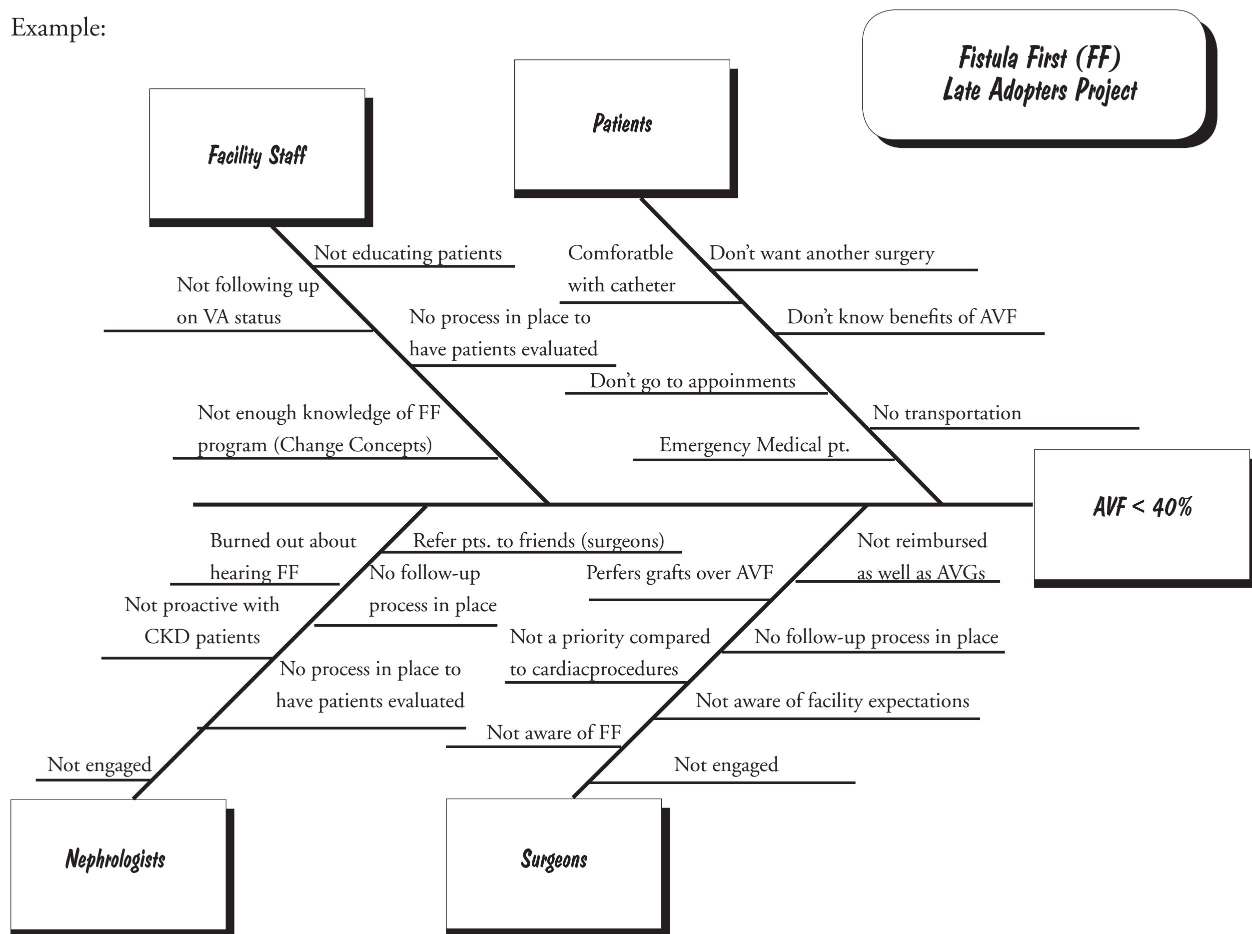
The fishbone diagram (also known as the Cause-& Effect diagram) identifies many possible causes for an effect or problem. It is useful in structuring a brainstorming session. It sorts ideas into useful categories. **When to use the fishbone diagram**: When trying to find possible causes for a problem.

How to complete the Fishbone Diagram

1. Determine the problem and create a problem statement (effect). Write it at the right center of the chart.
2. Brainstorm the major categories of causes of the problem. Write categories of causes as the main branches stemming from the center line.
3. Brainstorm all the possible causes of the problem. Ask “Why did this happen?” about each cause.
4. Write sub-causes stemming from the category of causes (action: something you did that contributed to the problem or condition: something that existed that contributed to the problem). Sub-causes will lead you to the root causes of the problem.
5. Collect data to confirm root cause.
6. If no further causes can be identified, then you have found the root cause of the problem.

Use what you have learned from this process and create a plan/resolution to improve it.

Example:



This material was prepared by Network 18 under contract #HHSM-500-2006-018 with the Centers for Medicare and Medicaid Services (CMS). The contents presented do not necessarily reflect the CMS policy.

Cause & Effect
Fishbone/Ishikawa
Diagram

Dialysis Adequacy Run Chart

Average Kt/V or URR

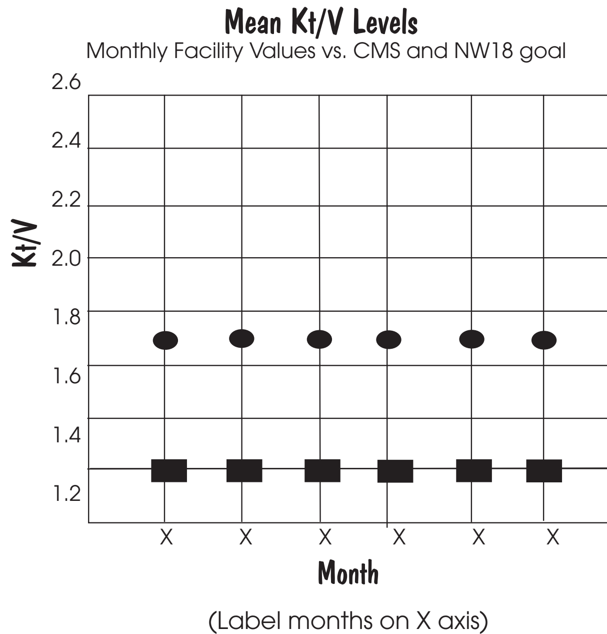
Facility Name: ______________________ Year: ______________

Provider # ______________

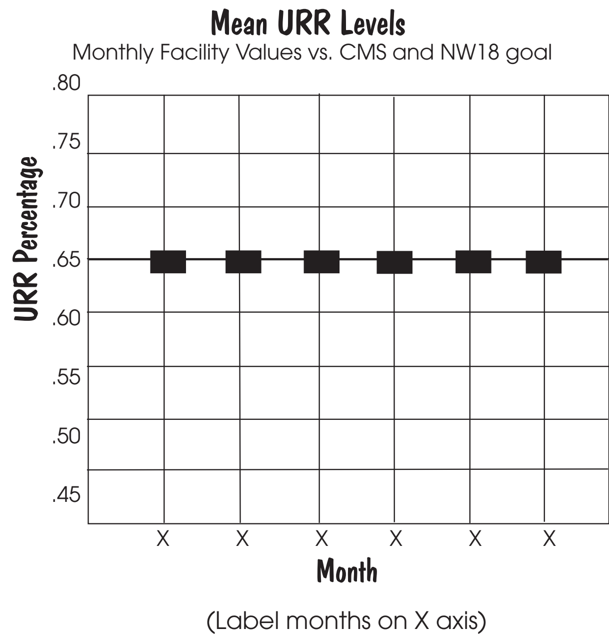
Avarage (Mean) Kt/V or URR By Month:

Month:	Month:	Month:
Month:	Month:	Month:

Plot the Average Kt/V or URR by month on the graph below for comparison to CMS and NW18 goal, and for trend identification.



(Label months on X axis)



(Label months on X axis)

Albumin Run Chart

Facility Name: ____ Year: __________

Provider # ____________

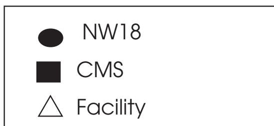
Which test for Albumin does your facility use? Please ✓ check one.

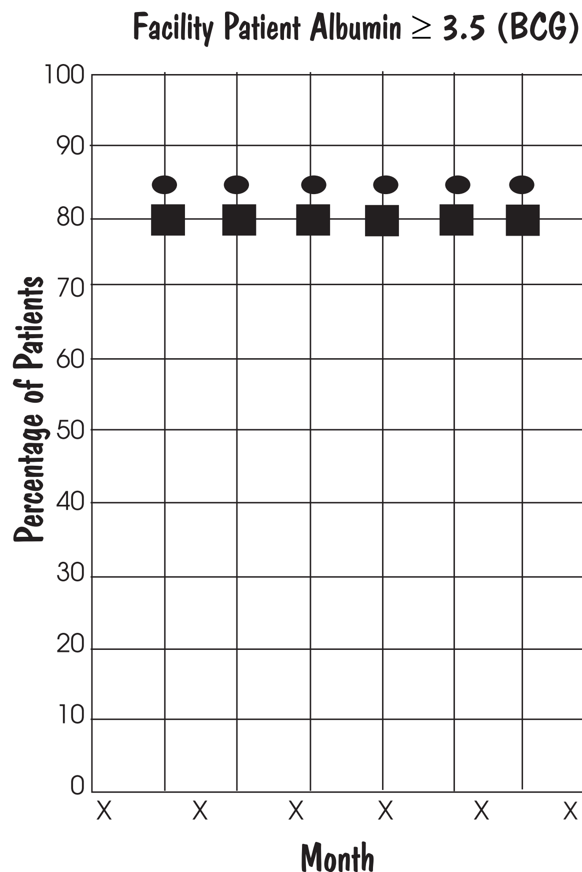
BCG (Bromcresol Grech) ❑ BCP (Bromcresol Purple) ❑

Please indicate what percentage of your facility patient population had Albumin ≥ 3.5 (BCG) or ≥ 3.2 (BCP).

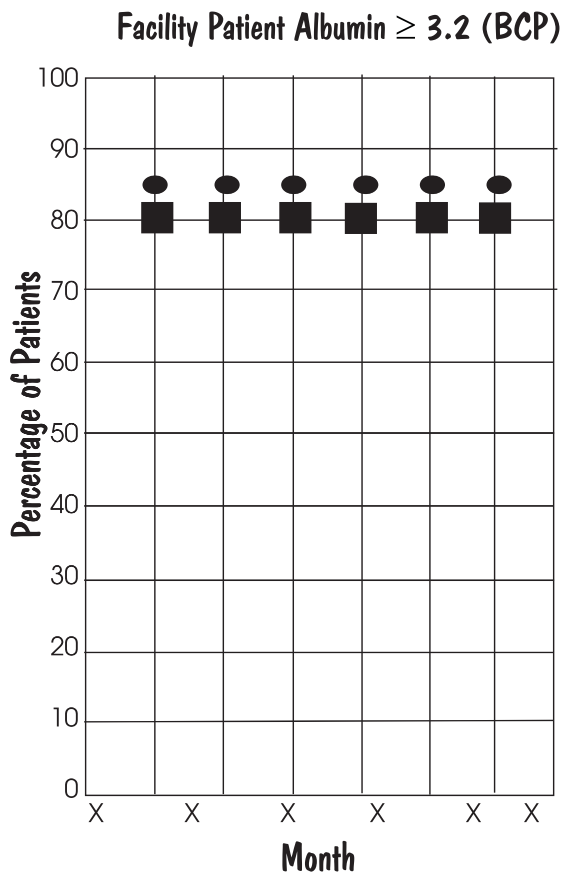
Month:	Month:	Month:
Month:	Month:	Month:

Plot your results by month on the graph below to compare with CMS and NW18 goal and for trend identification.





(Label months on X axis)



(Label months on X axis)

Anemia Run Chart

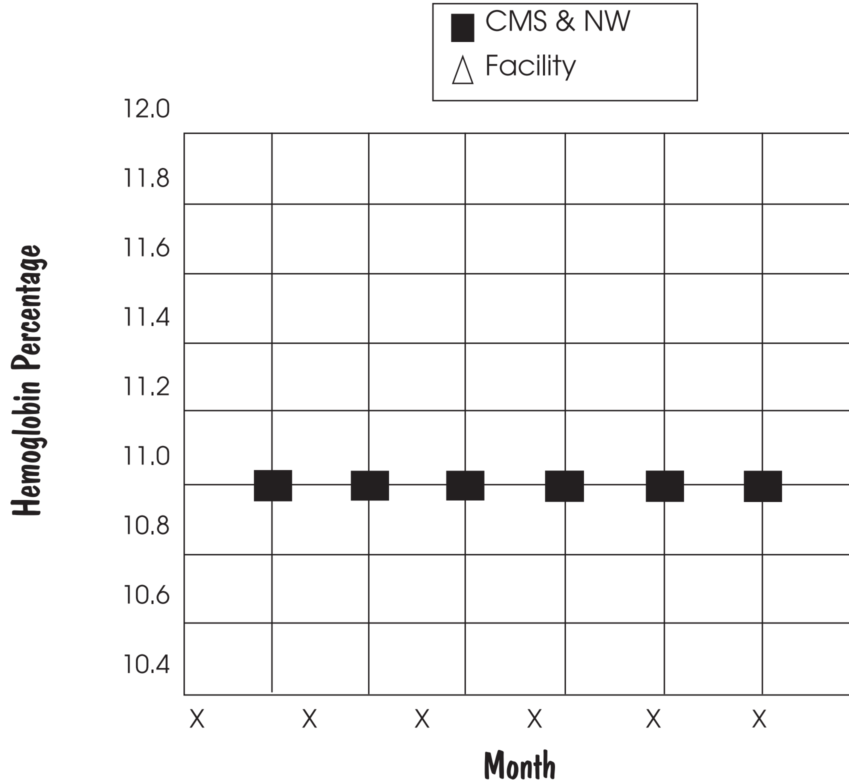
Facility Name: ___________________________________ Year: ________

Provider #: ____________

Average (Mean) Hemoglobin Levels By Month:

Month:	Month:	Month:
Month:	Month:	Month:

Plot the average hemoglobin level by month on the graph below for comparison to CMS and NW18 goal and for trend indentification.



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Corrective Action

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Quality Improvement: Facility Membership

The ESRD Conditions of Participation and Interpretive Guidelines require that all Medicare-certified dialysis and transplant facilities support Network goals and objectives and participate in Network activities and medical care evaluation (quality improvement) projects.

Under the 2008 CMS Conditions for Coverage for End Stage Renal Disease Facilities, 495.180, Standard V772: Relationship with the ESRD Network *"The dialysis facility must cooperate with the ESRD Network designated for its geographic area, in fulfilling the terms of the Network's current statement of work. Each facility must participate in ESRD Network activities and pursue Network goals".*

This requirement is confirmed through a Membership Agreement signed by an authorized individual on behalf of the facility. A Membership Agreement is completed at the time of initial certification and remains valid until a facility loses its Medicare certification, changes ownership or ceases operations.

Network staff monitors facility compliance with forms submission requirements and participation in quality improvement projects or studies on an ongoing basis. Failure to comply in a satisfactory manner will result in a Formal Improvement Plan (FIP) as described in Section 3.

Quality Improvement: Formal Improvement Plan (FIP)

Problem Identification

The Medical Review Board (MRB) will determine problems and/or facilities not in compliance with Network goals and objectives through:

- Review of the components of the Network Quality Improvement Standards. These include the annual Quality Assessment & Performance Improvement (QAPI) Report forms, Clinical Performance Measures (CPM), annual Centers for Disease Control (CDC) National Surveillance of Dialysis Associated Diseases, and Patient Grievance forms.
- Problems identified by CMS or Network special studies, e.g., Network Quality Improvement Projects (QIP), annual Network-wide clinical outcome indicators
- Facilities failing to participate in CMS or Network QI projects, or submit required study forms in a timely manner.

In general, it is expected that most problems will be resolved informally. If the MRB determines a problem, written notification will be sent to the facility, addressing what information or forms are missing or delinquent, and the time frame for responding (see flow chart). If responses are still not received in a timely manner, or the response to the initial inquiry is unacceptable, the MRB will request a Formal Improvement Plan (FIP).

Plan of Action

If the MRB requests a FIP, it must be completed by the appropriate clinical and administrative staff at the facility, and should include:

1. A recognition of the problem (what or who must change)
2. A description of goals and objectives to be achieved
3. A description of processes/measurements/tools to be used to assess and measure improvement (including what action will be taken and who is responsible for implementation)
4. A timetable for accomplishing the improvement plan (when must the change/correction occur and how will it be documented)

Assuring Correction (Resolution)

The effectiveness of the action must be assessed, using the following criteria:
1. Continue to provide data for review
2. Has care improved?
3. Has the problem been resolved?
4. Is it documented?

"Corrective Action/Improvement Plan"
Procedure

Facility Problem Identified By Network:

Feedback Letter or Memo to Nurse Manager

If No Response or Unsatisfactory Response,

"First Notice" FAX notification is sent to Nurse Manager

If No Response,

"Second Notice" letter sent to Facility Nurse Manager,

Copy to Facility Administrator

If No Response,

A "Letter of Explanation" (LOE) or a

Formal Improvement Plan is requested by Medical Review Board (MRB)

If No Response or Submission,

State Survey Agency (Licensing and Certification Division) notified for possible survey

If Problem Not Corrected,

MRB & Board of Directors makes SANCTION recommendation to CMS

Regional CMS Office Has Option to Terminate Medicare Program at Facility or to Recommend Alternative Sanction

Monitoring and Reporting Providers (Facilities) Not in Compliance With The Network Goals

Follow-Up Process

The process below serves as a general guideline for following up on identified problems.

1. Periodically, facilities are appraised of the Network goals and objectives. Facilities are also notified of the requirements for each new Quality Improvement Project.

2. Facilities will be notified of a problem or failure to comply as soon as the Medical Review Board identifies and reviews the 'problem'. Notification occurs within one month, unless the matter is life threatening.

3. A facility will be allowed 20 days to respond to the MRB's request for either a letter of explanation or a Formal Improvement Plan for an identified problem.

4. The CMS Project Officer (PO) will be notified if a sanction is recommended or the MRB, Board of Directors or Executive Director determines that such notification is warranted. A sanction will not be recommended unless a facility 'consistently fails' to meet Network goals and objectives; or consistently fails to follow recommendations of the MRB; or fails to permit MRB representatives to conduct an on-site review; or fails to submit data as required to prepare the annual report. The MRB has determined that they will review each non-compliance activity individually, and determine if the facility "consistently fails" accordingly.

5. The CMS Regional Office will be copied on any communication regarding the possibility of a sanction recommendation.

Recommendation of Sanctions/Alternative Sanctions

Policy

If a facility or provider fails the requirements in Section 1881©(3) of the Social Security Act to cooperate in achieving the goals and plans of the ESRD Network to which it belongs, and that failure does not jeopardize patient health and safety, the Centers for Medicare & Medicaid Services (CMS) Regional Office (RO) may impose sanctions as an alternative to terminating coverage of ESRD services furnished by that supplier (42CFR 405.2181).

SCRDC will maintain a plan for monitoring facilities/providers compliance with Network goals, distribute it to CMS and all facilities/providers in the Network area, and use it to identify facilities/providers that consistently fail to cooperate with Network plans/goals or to follow the recommendations of the Medical Review Board.

CMS imposition of a sanction will be based on a recommendation from the SCRDC Board of Directors that documents all prior steps taken by the Network to achieve satisfactory participation over at least a 90-day period.
If at any time while conducting SCRDC contract activities, the Network identifies situations or collects information that a physician may be failing to meet his/her obligation to provide quality care, SCRDC will refer the issue to the QIO for peer review and notify the Project Officer of the situation and action taken.

Procedure

1. The SCRDC Monitoring Plan is used to identify facilities that consistently fail to cooperate with Network 18 plans and goals or to follow the recommendation of the Medical Review Board (MRB). The Monitoring Plan will reference Quality Improvement, Patient Services and Information Management projects/activities required of all facilities as well as those activities that are facility-specific.

2. The Alternative Sanctions policy and Monitoring Plan will be disseminated to all facilities on an annual basis via a special mailing. This mailing will review current Network projects, resources and data requirements. The cover letter will contain a citation regarding the statutory requirements for a facility to cooperate with Network goals and objectives.

3. SCRDC staff will review the Monitoring Plan on at least a monthly basis and communicate concerns about facility compliance with Network goals.
   - Initial communication will be via telephone or letter to facility Management and Medical Director to review the issues and request a Letter of Explanation or evidence of compliance.
   - The facility's failure to reply, unsatisfactory reply or continued lack of participation/improvement within 30 days will result in referral to the Medical Review Board and request for a written Formal Improvement Plan (FIP).

A Formal Improvement Plan includes recognition of the problem, a description of goals and objectives to be achieved, a description of processes/measures/tools to be used to assess and measure improvement, and a timetable for implementing the plan. SCRDC will assess the efficacy of the facility's improvement plan/activities through review of process/outcomes data, facility documentation of its activities, evidence that appropriate administrative and clinical personnel were involved, and other evidence that quality improvement tools/resources were applied.

4. If, after a period of at least 90 days, the SCRDC staff and MRB have exhausted all reasonable efforts to gain facility compliance, and has documented that the facility failed to cooperate with Network 18 goals and objectives, the MRB may request the SCRDC Board of Directors to recommend CMS imposition of an alternative sanction. SCRDC will consider the nature of the compliance issue (e.g., patient outcomes), the length of time over which non-compliance has occurred, CMS contractual requirements involved, and other relevant issues in its deliberations. SCRDC will also consult with the CMS RO Project Officer to determine if there is sufficient documentation to proceed with a sanction recommendation based on the facility's failure to meet Network goals and its impact on SCRDC's ability to meet its contractual obligations.
5. The Alternative Sanction documentation submitted to the CMS RO Project Officer will describe the details of the problem situation and that the facility is still not in compliance with Network 18 goals and plans. The documentation will clearly and specifically describe how the facility fails to cooperate and meet performance expectations in regards to Network 18 plans or goals and/or fails to follow MRB recommendations.

6. The following written documentation will accompany and support the Alternative Sanction recommendation:
   - Documentation that the facility was notified in writing of Network goals
   - Documentation of the goal, objective or plan that the facility has failed to meet
   - Actions that Network 18 took to inform the facility that it was not complying with Network goals, objectives or plans
   - Documentation that the facility was given an opportunity to make corrections
   - Follow-up actions taken to resolve the problem (e.g., documentation of phone calls to the facility asking for specific information) that demonstrate Network 18's attempts to work with the facility to resolve the problem
   - Documentation of the facility's failure to submit an action plan, or the submission of an unacceptable action plan, if applicable

7. Upon SCRDC Board of Directors approval, Network 18 will advise the CMS Project Officer of its intent to recommend a sanction after fully documenting, in writing, the facility's failure to comply with Network goals and objectives. SCRDC will submit two (2) copies of the documentation, organized in notebook form, and a cover letter addressed to the CMS Region IX Associate Regional Administrator (ARA) who services California through the SCRDC Project Officer at CMS Region X. The documentation will include:
   - Name, address and Medicare provider number of the involved facility
   - The Network goal or objective with which the facility failed to comply
   - A brief summary of the basis for the sanction recommendation

- An outline of what documentation the facility must submit and the action(s) the facility must take in order to remove the sanction
- The individual in the Network whom the RO can contact for further information and assistance
- The name and phone number of the SCRDC Project Officer

8. Network 18 will provide any additional assistance and information the CMS RO may need to make a final determination whether to sanction the facility.
9. The facility and Network 18 will be notified by CMS RO about the reasons for the sanction and its effective date.

10. The alternative sanction will remain in effect until CMS determines that the dialysis facility is making a reasonable effort and is in substantial compliance with the requirement to cooperate in Network 18 plans and goals. Network 18 may serve as a resource to the facility in its efforts to achieve compliance, and assist the RO in verifying the facility's compliance with the requirements.

11. Network 18 staff will inform the Board of Directors of the status of an alternative sanction action at least monthly, and more often if necessary, via Executive Committee conference calls, and include the matter on the quarterly Board of Directors and Medical Review Board meeting agendas.

Approved: July 2007

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