



Tune-Up to Speak Up: Improving the Grievance Process Toolkit

Purpose

The purpose of this document is to provide some general guidance for incorporating the Tune Up to Speak Up resources into your facility Quality Assessment and Performance Improvement (QAPI) activities. It provides a brief description of QAPI and some of the standardized quality tools and methods, as well as several checklists to help you get started.

Quality Assessment and Performance Improvement (QAPI) Brief Overview

Under the end-stage renal disease (ESRD) Conditions for Coverage every dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven QAPI program with participation by the professional members of the interdisciplinary team (IDT). The program must reflect the complexity of the organization and services (including those under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its QAPI program including continuous monitoring for Centers for Medicare & Medicaid Services (CMS) review.

What is QAPI?

Quality Assurance: Ensuring compliance, and follow up of known issues. Conducting a root cause analysis is a way in assure quality.

Performance Improvement: A focus on issues that result in poor outcomes.

- It is an ongoing evaluation of operating systems and clinical process rather than individual problems.
- It is data driven.
- It is an ongoing program that achieves measurable improvements in health care.

PDSA cycle

One standard quality improvement tool that is frequently used is the Plan-Do-Study-Act (PDSA) cycle for improvement. The PDSA cycle is shorthand for testing a change by developing a plan to test the change (Plan), carrying out the test (Do), observing and learning from the consequences (Study), and determining what modifications should be made to the test (Act). After testing a change on a small scale, learning from each test, and refining the change through several PDSA cycles, the team may implement the change on a broader scale — for example, incorporating into the facility policy and procedure.

Plan

1. Select the opportunity for improvement
2. Select the team
3. Study the current situation
4. Analyze the causes
5. Develop a theory for improvement

Do

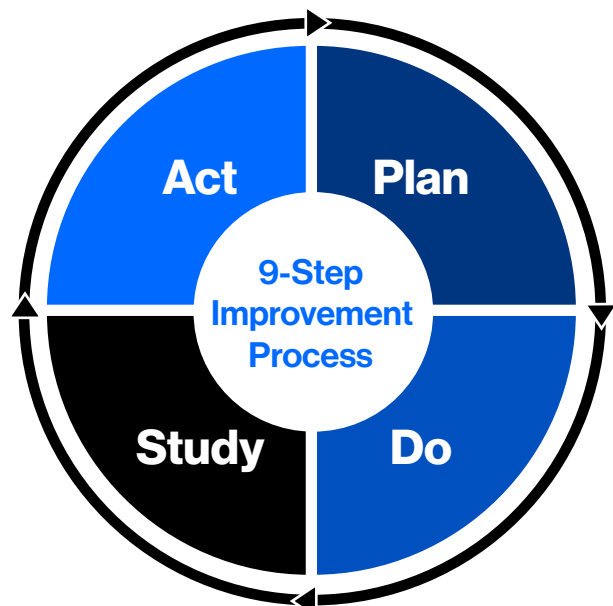
6. Implement the improvement

Study

7. Study the results

Act

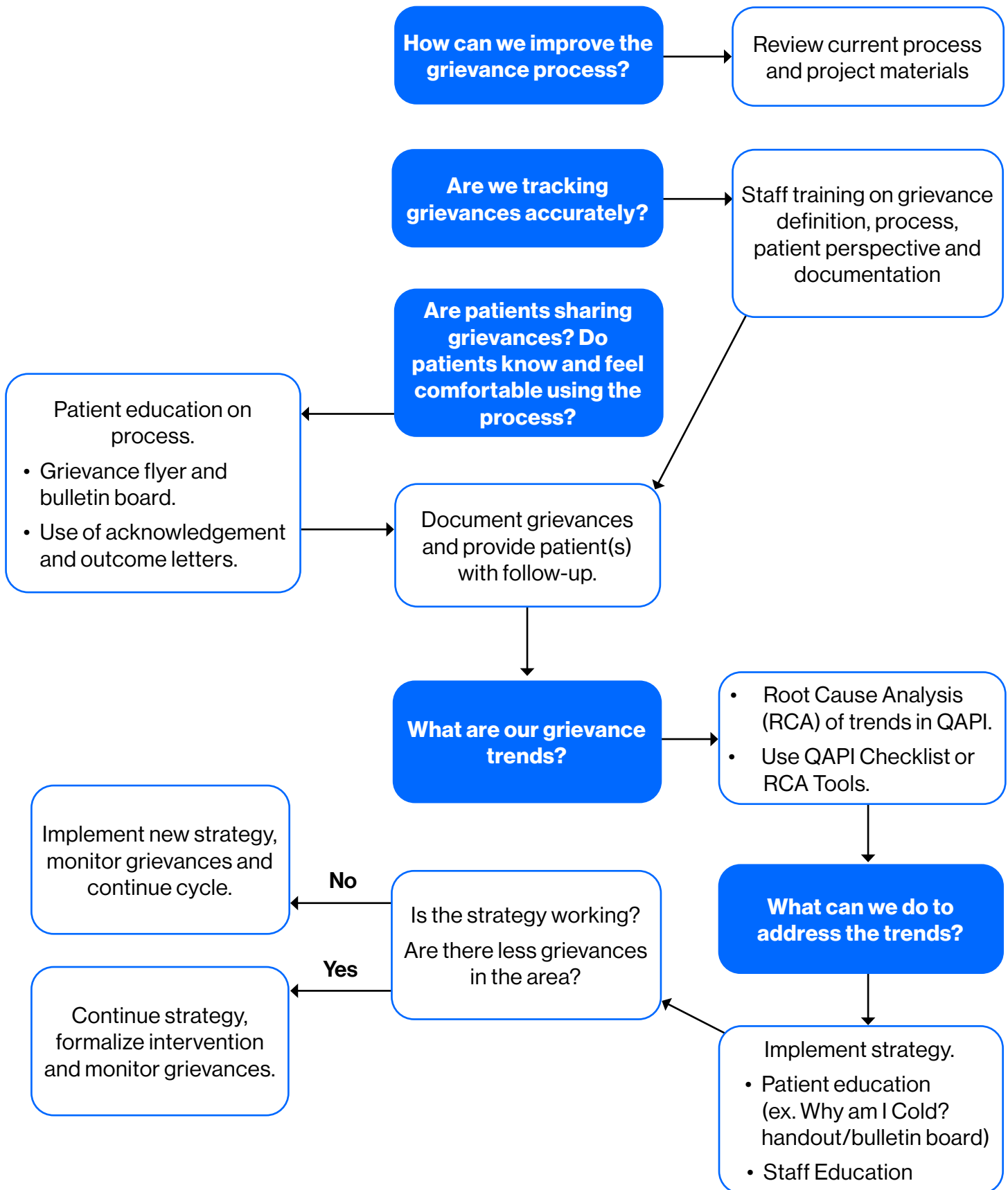
8. Establish a future plan
9. Standardize the improvement



PDSA Worksheet

	Steps	Explanation	Example
Plan	1. Select team facilitator and team members.	Team members are people with personal knowledge of the processes and systems involved in investigating the grievance.	- Required QAPI team members - Patient representative - Project lead should be Facility Administrator or social worker. - All staff should document grievances.
	2. Select the opportunity for improvement. Define the problem.	Events and issues can come from many sources (e.g., grievance log, patient satisfaction results). The facility should have a process for selecting events that will undergo a Root Cause Analysis.	- Patients are consistently complaining of temperature or communication concerns. - Our facility has not had any, or very few, complaints reported.
	3. Study the current situation.	Gather preliminary information and collect data needed to understand the issue.	- Grievance logs, identify trends in QAPI meetings, individual grievances should not be discussed. - Patient satisfaction and facility culture of safety. Do patients feel comfortable voicing concerns? - Collect and organize the facts surrounding the grievance trends to understand what is happening.
	4. Analyze the causes. Conduct a Root Cause Analysis (RCA).	A thorough analysis of contributing factors leads to identification of the underlying process and system issues (root causes) of the grievance trends.	- Use the “five whys” technique by asking “why is that?” - Use the fishbone tool. - If you don’t have many grievances: “Why don’t we have grievances?”
	5. Develop a theory for improvement.	The team determines how best to change processes to reduce the chance of another similar grievance.	- How can we change the way we do things to make sure this root cause does not result in a future grievance? - Will all current and new staff be educated on the changes to prevent reverting to the old way of addressing concerns?
Do	6. Implement Solutions.	The team determines how best to change processes to reduce the chance of another similar grievance.	- Who will implement the solutions, by when and how? - Use of patient educational resources for example the “Why am I Cold” resource.
Study	7. Measure success.	The team looks at current trends and compares to previous numbers to see how successful interventions were.	- Did we see progress? - Do we need any further interventions?
Act	8. Establish a future plan.	The team discusses their plan to continue process or modify interventions.	How can we incorporate this process and interventions into our policy and procedure?
	9. Standardize improvements.	The team discusses their plan to continue process.	How can we incorporate this process and interventions into our policy and procedure?

PDSA Cycle Grievance Process Improvement



Grievance Process Improvement Startup Checklist

1. Review project overview with three components and initial steps to be completed with your team:

Process Tune Up

- Review Policy and Procedure
- Use CMS definition of grievance
- Educate staff
- Use CMS tools to track all grievances

Patient Partnership

- Identify Peers in Action
- Review Network info on engaging patient in QAPI

“Take 5 to Tune In”

- Review intervention strategy and determine if appropriate
- Pre-Assessment questionnaires
- Conduct staff training

2. Review the CMS definition of grievance:
A grievance is defined as: “A written or oral communication from an ESRD patient, and/or an individual representing an ESRD patient, and/or another party, alleging that an ESRD service received from a Medicare-certified provider did not meet the grievant’s expectations with respect to safety, civility, patient rights, and/or clinical standards of care.”
3. Review current Facility Grievance Policy and Procedure on page 6.
4. Review relevant ESRD Conditions for Coverage on pages 9-12.

Grievance Policy and Procedure Review

Policy and procedure should include:

1. A statement that the patient has the right to file a grievance without fear of reprisal or denial of services.
2. A statement that the patient has the right to file a grievance with the Network and/or state without first using the facility's internal grievance process.

Note: If the Network/State information is stated as a step within or following the internal process, it is implied that the patient must go through the facility first.

3. A clearly defined procedure for the submission of grievances.
4. A clearly defined implementation process that allows the patient to file an oral or written grievance with the facility, including an option to file anonymously.

Note: Patients should be able to file a grievance verbally and not be required to submit anything in writing. This can become a barrier for patients and may not address the patients' right to receive information in a way s/he can understand.

5. List specific timeframes for a grievance to be acknowledged, investigated and addressed by staff.
6. A description of how the patient, or the patient's designated representative, will be informed of steps taken to resolve the grievance.
7. Network contact information that is correct and complete:

ESRD Network 16

3725 Champion Hills Drive, Ste. 3100
Memphis, TN 38125
Toll-Free: 800-456-6919

ESRD Network 17

3725 Champion Hills Drive, Ste. 3100
Memphis, TN 38125
Toll-Free: 800-444-9965

It is not necessary to have information about the Network policy/procedure, only to have the Network contact information. There are no forms for them to complete. They only need to call us. You can refer the patient to the [Network website](http://esrd.qsource.org) (esrd.qsource.org) if they would like to see information on our procedure.

Please remove any outdated information about the Network.

8. State information that is correct and complete (see next page).

Are there any changes that need to be recommended to the Governing Body to update the policy and procedure to reflect the current standards?

Note: If the facility is part of a corporation, the facility must have the ability to make changes at the local level.

Network 16 State Survey Agency Information

Alaska Department of Health

Phone: (907) 334-2483

Toll Free: (888)-387-9387

Idaho Department of Welfare

Phone: (800) 345-1453

Fax: (208)-364-1888

Montana Department of Public Health & Human Services

Phone: (800) 762-4618

Oregon Health Authority

Phone: (971) 673-0540

Fax: (971) 673-0556

Washington State Department of Health

Phone: (800) 633-6828

Network 17 State Survey Agency Information

San Fransico Regional Office

Phone: (415) 744-3501

US Territories Served: American Samoa, Guam and Northern Mariana Islands

Hawaii Department of Health

Phone: (808) 692-7420 or (833) 886-8811

Northern California Field Operations Branch – District Offices

Chico District Office

Phone: (800) 554-0350

Email: CDPH-LNC-CHICO@cdph.ca.gov

Counties served: Butte, Colusa, Glenn, Lassen, Modoc, Nevada, Plumas, Shasta, Sierra, Siskiyou, Sutter, Tehama, Trinity, Yuba

East Bay District Office

Phone: (510) 620-3900

Email: CDPH-LNC-EASTBAY@cdph.ca.gov

Counties Served: Alameda, Contra Costa

Fresno District Office

Phone: (559) 437-1500

Toll Free: (800) 554-0351

Email: CDPH-LNC-FRESNO@cdph.ca.gov

Counties Served: Fresno, Kings, Madera, Mariposa, Merced, Stanislaus

Sacramento District Office

Phone: (916) 263-5800

Toll Free: (800) 554-0354

Email: CDPH-LNC-SACRAMENTO@cdph.ca.gov

Counties Served: Alpine, Amador, Calaveras, El Dorado, Nevada, Placer, Sacramento, San Joaquin, Sierra, Solano, Yolo, Tuolumne

Note: The Sacramento District Office oversees San Joaquin County's hospitals, clinics, end-stage renal disease facilities, congregate living health facilities, and adult day health care facilities

San Francisco District Office

Phone: (415) 330-6353

Toll Free: (800) 554-0353

Fax: (415) 330-6350

Email: CDPH-LNC-DALYCITY@cdph.ca.gov

Counties Served: San Francisco, San Mateo, Santa Clara (Parts of: Cupertino, Los Altos, Mountain View, Palo Alto, Santa Clara, Saratoga, Sunnyvale)

San Jose District Office

Phone: (408) 277-1784

Toll Free: (800) 554-0348

Fax: (408) 277-1032

Email: CDPH-LNC-SANJOSE@cdph.ca.gov

Counties Served: Monterey, Santa Clara (Parts of: San Jose, Los Gatos, Campbell, Milpitas, Morgan Hill, Gilroy), San Benito, Santa Cruz

Santa Rosa/Redwood Coast District Office

Phone: (707) 576-6775

Toll Free: (866) 784-0703

Email: CDPH-LNC-SANTAROSA@cdph.ca.gov

Counties Served: Napa, Marin, Sonoma, Mendocino, Humboldt, Lake, Del Norte

Stockton District Office

Phone: (209) 957-6948

Toll Free: (888) 398-6660

Email: CDPH-LNC-STOCKTON@cdph.ca.gov

Counties Served: Amador, Calaveras, San Joaquin, Stanislaus, Toulumne

Relevant Sections from the ESRD Conditions for Coverage

§ 494.70 Condition: Patients' Rights		
Tag #	Regulation	Interpretive Guidance
V452	(a) Standard: Patients' rights. The patient has the right to– Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD;	In all verbal and nonverbal communications, patients must be treated with respect, dignity and sensitivity. Interactions among patients, staff and others should demonstrate observance of patients' rights and consideration of a patient's physical condition, emotional state, and cultural background. Patient must be able to question procedures or staff performance without fear of reprisal.
V465	The patient has a right to– (14) Be informed of the facility's internal grievance process;	Each facility should develop and implement an internal grievance process, as is stated in the Condition for Governance at V765. Facility staff must inform patients about the internal grievance process and the steps to follow for filing an internal grievance. Refer to V765 for the components of the internal grievance process. Use those tags for failure to implement the process. Use this tag for failure to inform patients about the process.
V466	(15) Be informed of external grievance mechanisms and processes, including how to contact the ESRD Network and the State survey agency;	The facility must establish a procedure for informing patients about seeking external help to resolve grievances that cannot be resolved internally or if patients are not comfortable using the internal process. The facility staff must inform each patient/ designee how to contact the appropriate external entity to file a grievance, including the ESRD Network and the State survey agency. Refer to V470 for the requirement of posting contact information for the Network and State survey agency.
V467	(16) Be informed of his or her right to file internal grievances or external grievances or both without reprisal or denial of services; and (17) Be informed that he or she may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing.	Every patient must be free to file a complaint or grievance within the facility or externally with the ESRD Network or State survey agency. Facility staff should inform patients that they can file a grievance anonymously or through a representative without being afraid that they will be treated differently or denied services. "Reprisal" would include retaliation or revenge and could include perceived punishment, isolation, the intentional infliction of physical pain or emotional distress or involuntary discharge from the facility.

V470	(c) Standard: Posting of rights. The dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients.	The facility must post all of the rights listed in V452-V469 in a common area of the facility which is routinely available to in-center and home dialysis patients. This posting is meant to augment, not substitute for communicating these rights to each individual patient in a way the patient can understand. Information that must be posted includes the list of patient rights and the mailing addresses and contact information for the applicable ESRD Network and State survey agency, as well as the complaint telephone numbers for each.
§ 494.110 Condition: Quality Assessment & Performance Improvement		
V625	§ 494.110 Condition: Quality assessment and performance improvement.	This Condition looks at facility aggregate data and requires facility-based assessment and improvement of care, while the Plan of Care Condition expects patient-based improvement of care. Compliance with this Condition is determined by review of clinical outcomes data and the records of the quality assessment performance improvement activities of the facility, and by interviews of responsible staff including the medical director. Non-compliance at the Condition level may be warranted if a pattern of deficient practices which could impact patient health and safety is identified. Examples include, but are not limited to: • Absence of an effective QAPI program; • Failure to recognize and prioritize major problems that threaten the health and safety of patients; or • Failure to take action to address identified problems.
v636	(viii) Patient satisfaction and grievances.	The intent of QAPI in this area is to use patient satisfaction surveys and patient grievance investigations as a means to identify opportunities to improve care. The survey should be non-threatening and be conducted in a manner to protect the patient's identity. QAPI discussion of patient satisfaction survey results and patient grievance information should focus on the use of data to inform the care delivery system. If needed changes are identified, there should be evidence of action taken to implement those changes. Facilities must monitor and track patient grievance reports and outcomes as required at V765; use that tag for issues related to responding to individual grievances.

v638	(b) Standard: Monitoring performance improvement. The dialysis facility must continuously monitor its performance; take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time.	“Continuously monitor” requires that outcome data, achievement of treatment goals, adverse events, infections, falls, errors, etc. be monitored as this data is available or these events occur. Tracking and trending, analysis of root causes, development of improvement plans, implementation of those plans, evaluation of the success of the plan, and revision of the plan must occur as indicated. Once improvement is made, the facility must have a mechanism to ensure that improvement is sustained. This could include practice audits, review of records, or repeat patient satisfaction surveys, etc. The medical director should continuously communicate with the governing body about the status of QAPI activities, particularly when resources are required to address program improvements. See V756. If the medical director is a part of the governing body, there should be some evidence he/she provides information to members who do not participate in the QAPI meetings. The minutes of the governing body or the minutes of the QAPI committee should demonstrate communication between the governing body and the medical director. Refer to V756 for the requirements related to the responsibilities of the governing body for QAPI.
§ 494.180 Condition: Governance		
V750	§ 494.180 Condition: Governance.	This Condition addresses the overall management of the facility. It requires that an identifiable governing body demonstrate responsibility for the operation of the facility, including fiscal management, staff training and coverage, medical staff appointments and coverage, and the QAPI program. This Condition also holds the governing body accountable for establishing an internal grievance process and decreasing the potential for involuntary discharge of patients; for emergency coverage and backup; for electronic data submission; and the relationship of the facility to the ESRD Network.

V755	(3) The relationship with the ESRD networks; and	The ESRD Networks are CMS contractors assigned responsibilities via a Statement of Work to: • Collect and analyze data on ESRD patients and their outcomes of care, including the information that allows patients to be enrolled into the ESRD Medicare benefit program • Provide education and oversight to improve the quality of care delivered to dialysis and kidney transplant patients • Support facilities in developing and maintaining an effective QAPI program • Respond to complaints and grievances At the time of publishing these regulations, there were 18 ESRD Networks, each covering a specified geographic area. A signed agreement between the facility and the applicable Network is required prior to the initial certification survey. The CEO or administrator is responsible to receive and act on correspondence from the ESRD Network and to promptly respond to any request from the applicable Networks. Additional requirements related to Networks are found at V772.
V765	(e) Standard: Internal grievance process. The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services. The grievance process must include— (1) A clearly explained procedure for the submission of grievances. (2) Timeframes for reviewing the grievance. (3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance.	The facility's policies and procedures must describe all available grievance procedures to the patient. The facility must inform the patient and/or the patient's designated representative (also called "designee") of its internal grievance process. Refer to the requirement at V465 under the Condition for Patients' rights. Each facility must implement a process to ensure that there will be no reprisal or denial of services for any patient who files an internal grievance and the grievance procedure will be clearly explained to patients. The existence of grievances should not be viewed negatively, as this would be an indication that patients understand the internal grievance process and believe that filing a grievance will not result in reprisal or denial of services. Lack of grievances does not indicate a lack of an internal grievance process. The facility's grievance process should assure those grievances involving situations or practices that place patients or staff members in immediate danger (e.g. the patient's grievance brings attention to hazardous environmental conditions) are resolved immediately. The facility's process must include clearly defined timeframes for a grievance to be acknowledged, investigated, and addressed. Timeframes should be sufficient to conduct an investigation yet ensure that the grievance is addressed in a timely manner. The patient/designee should be informed of the status of the investigation periodically, and when resolution is attained or considered attained by the facility. Each grievance should demonstrate a completed cycle of reviewing the grievance and reporting back to the patient.

V772	(i) Standard: Relationship with the ESRD network. The governing body receives and acts upon recommendations from 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.	The ESRD facility must respond promptly within any specified deadlines to requests for information, data, or corrective action plans from its ESRD Network. The facility must participate in Network projects and activities aimed at addressing identified needs and improving quality of care in the individual facility or the Network-wide area. Facilities may easily obtain copies of their Network's goals and objectives as each Network is required to post their annual report on their website. These reports include the individual Network's goals and activities. At the time of publication of these regulations, the goals of ESRD Networks were to: • Improve the quality and safety of dialysis-related services provided for individuals with ESRD. • Improve independence, quality of life, and rehabilitation (to the extent possible) of individuals with ESRD through encouragement of transplantation, use of self-care modalities (e.g., home peritoneal dialysis, home hemodialysis, and in-center self-care), as medically appropriate, through the end of life. • Encourage and support collaborative activities to ensure achievement of these goals through the most efficient and effective means possible, with recognition of the differences among providers (e.g., independent, hospital-based, member of a group, affiliate of an organization) and the associated possibilities/capabilities. • Improve the collection, reliability, timeliness, and use of data to: measure processes of care and outcomes; maintain the patient registry; and support the ESRD Network program.
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Monthly QAPI Suggested Checklist

	Checklist Question	Action Completed (document in minutes)
What is our progress on the grievance process interventions?		
Process Tune Up	1. Have we educated all staff on the grievance definition and process, reviewed the staff grievance poster and grievance recording process? How is staff responding to patient grievances?	☐ CMS definition of grievance ☐ Staff grievance poster ☐ Grievance logs ☐ Staff Education with Huddle Sheets
	2. Are we using the grievance logs to document all patient grievances?	☐ Review with staff. ☐ Review who is in charge of following up with patients regarding their concerns.
	3. What have our grievances been during this period?	☐ Use data provided by the Network to look for trends in grievance
	4. Where are we in the PDSA cycle?	☐ Use PDSA Worksheet
What are the patient partnership activities we have done this month?		
Patient Partnership	5. Do we have a Peers in Action? If not, who would be a good choice at our clinic?	☐ Identify Peers in Action ☐ Complete Peers in Action Application
	a. If so, how can we engage the Peers in Action? What are their interests in working with the team on this improvement activity?	☐ Discuss with Peers in Action their level of involvement options
	b. Would they be willing/able to attend QAPI meetings (if only the grievance discussion part as necessary) to discuss grievance trends with QAPI team and provide ideas/ feedback?	☐ Invite Peers in Action to QAPI ☐ Invitation Resource
	c. How are we using the Peers in Action to assist with this activity?	☐ Attend QAPI meeting ☐ Discuss grievance trends and ideas prior to or at QAPI meeting ☐ Assisting with Bulletin Boards ☐ Assisting with Take 5 Monthly Topics ☐ Assisting with other patient engagement activities
What is our progress with the "Take 5 To Tune In" sessions?		
Take 5 to Tune In	6. Patient involvement.	☐ Distributed Pre-assessments ☐ Distributed invitations to participate ☐ Completed ____ # sessions ☐ Patient feedback to share?
	7. Staff Involvement	☐ Reviewed the instructions and script with all staff? ☐ Scheduled staff training ☐ Completed staff training ☐ Distributed random notecards ☐ Documented staff feedback
	8. Evaluation	☐ Reviewed Pre-Assessments ☐ Distributed Post-Assessments ☐ Reviewed Post Assessments
Are we on target to meet our goals?		☐ Yes ☐ No

Root Cause Analysis

What is a Root Cause Analysis?

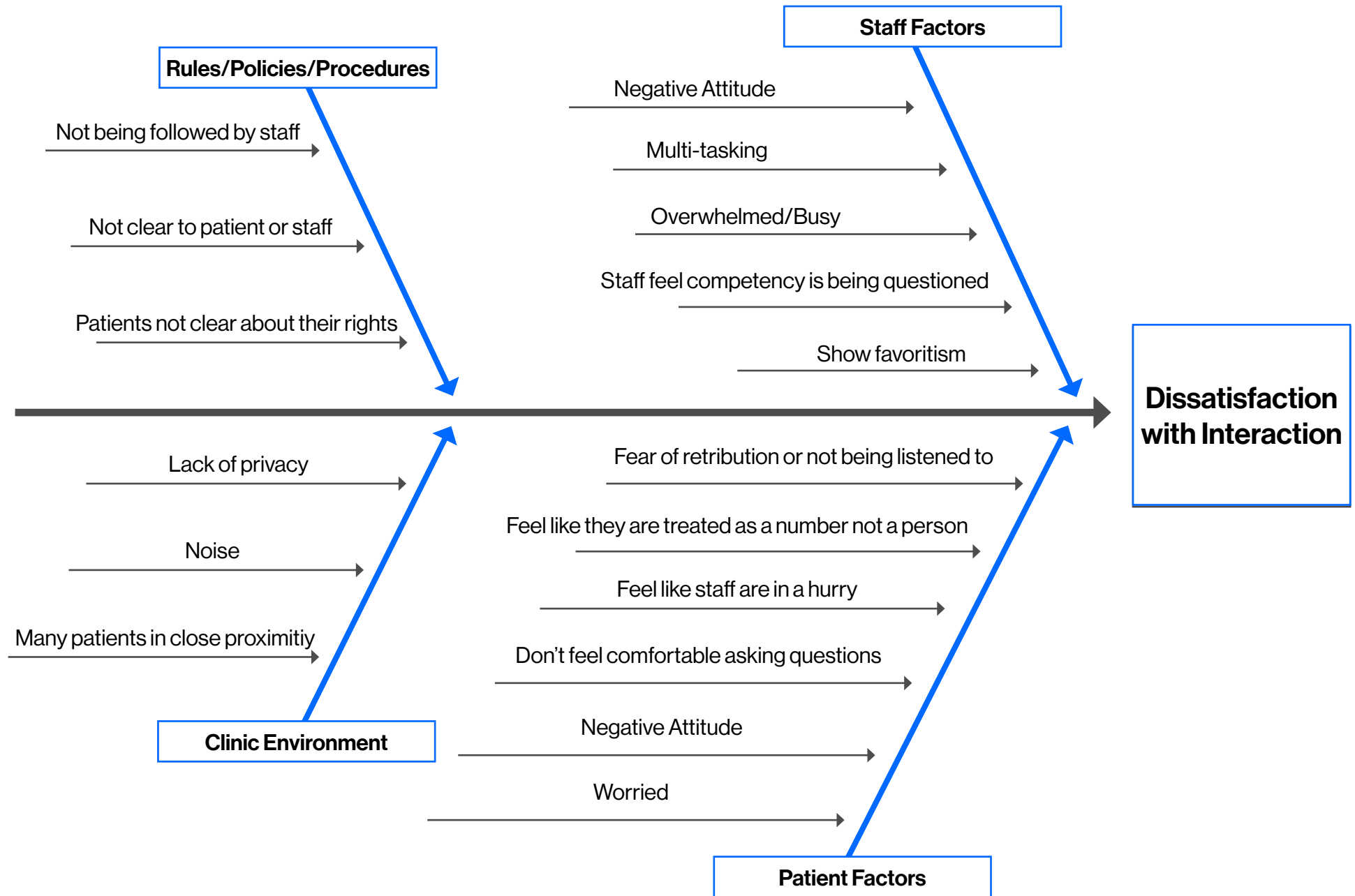
Just as you would pull a weed out of your garden by its root to ensure that it doesn't grow back, getting to the root cause of a system's issue is important to prevent the problem from returning. There are many formalized root cause analysis tools.

Two easy-to-use tools are the **Fishbone Diagram** and the **Five Whys**.

Fishbone (Cause-and-Effect) Diagram

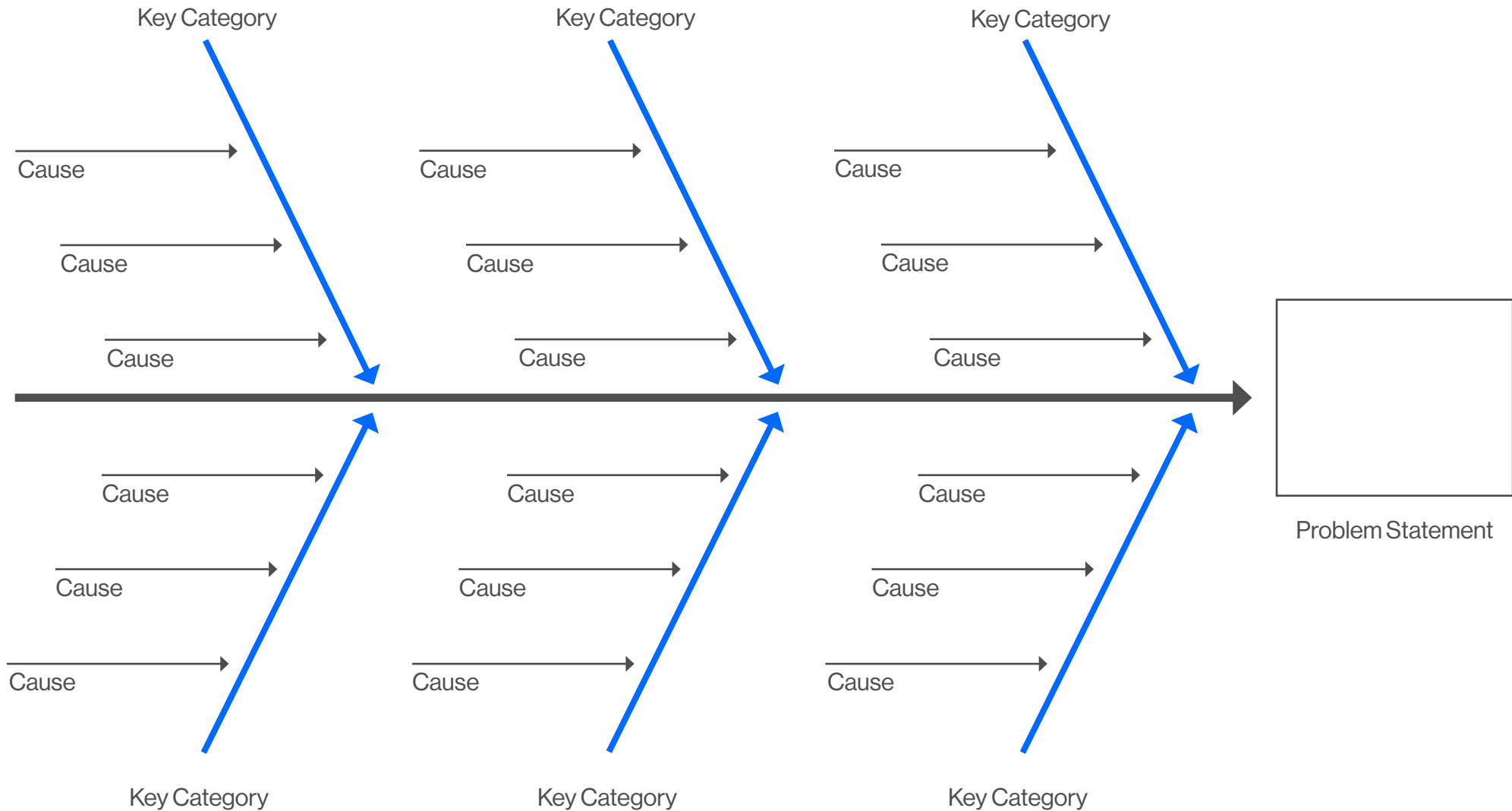
1. Begin the fishbone diagram by placing the problem at the head of the "fish."
2. Under each general category of the fishbone, answer the question, "Why?" for the identified problem. For example, "Why are people the cause of this problem?"
3. Once your team has completed the fishbone diagram, discuss the various causes to get to the root of the problem. It is from this discussion that the focus for the improvement plan can begin.

Fishbone Diagram Example



Fishbone Diagram Worksheet

1. Define the problem. Type or write this in the problem statement box to the far right.
2. Decide on key categories of the problem. Write or type these categories inside the rectangular boxes.
3. Brainstorm all the possible causes of the problem. Ask "Why does this happen?" Write or type these causes as a branch of the appropriate category. Causes can be written in several places if they relate to several categories. Continue to ask "Why?" and generate deeper levels of causes.



Five Whys

The Five Whys tool aids in identifying the root cause(s) of a problem. Begin by identifying a specific problem, and ask why it is occurring. Continue to ask “Why?” to identify causes until the underlying cause is determined. Each “Why?” should build on the previous response. There is nothing magical about the number five. Sometimes a root cause may be reached after asking “Why?” just a few times; at other times, deeper questioning is needed.

1. Define a problem; be specific.
2. Ask why this problem occurs, and list the reasons in Box 1.
3. Select one of the reasons from Box 1 and ask, “Why does this occur?” List the reasons in Box 2.

Continue this process of questioning until you have uncovered the root cause of the problem. If there are no identifiable answers or solutions, address a different problem or reason.

The Problem: _____

Why Does this occur?

Tip: Don't list five different reasons for the problem. Instead, dig deeper into the one reason.

1.		← Why is that?
2.		← Why is that?
3.		← Why is that?
4.		← Why is that?
5.		← Why is that?

Tip: If the last answer is something that can't be controlled, return to the previous answer. Individuals should not be blamed. Instead, the "why" is being examined to determine a solution/resolution.

Action to Begin Implementing:

Additional Resources

Continuous Quality Improvement (CQI) Strategies to Optimize your Practice. (April 30, 2013) The National Learning Consortium.

https://www.healthit.gov/sites/default/files/tools/nlc_continuousqualityimprovementprimer.pdf

QAPI Toolkit: The Forum of ESRD Networks.

<https://esrdnetworks.org/toolkits/professional-toolkits/qapi-toolkit/>

Dialysis Patient Grievance Toolkit (2016). The Forum of ESRD Networks.

<https://esrdnetworks.org/toolkits/patient-toolkits/dialysis-patient-grievance-toolkit/>

ESRD Program Interpretive Guidance for 42 CFR Part 494 Conditions for Coverage for ESRD facilities.

<http://www.cms.gov/GuidanceforLawsAndRegulations/Downloads/esrdpgmguidance.pdf>



Qsource ESRD Networks
3725 Champion Hills Drive, Ste. 3100
Memphis, TN 38125

Email: ESRDNetworks@qsource.org

Website: esrd.qsource.org

Network 16

Patient Services Line: (800) 456-6919

General Information: (317) 257-8265

Network 17

Patient Services Line: (800) 444-9965

General Information: (816) 880-9990