
Fistula First Breakthrough Initiative Root Cause Analysis

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Fistula First Breakthrough Initiative Root Cause Analysis

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Fistula First Breakthrough Initiative Root Cause Analysis Report

Introduction

The Fistula First Breakthrough Initiative (FFBI) contract required the contractor, Mid-Atlantic Renal Coalition, which also serves as End Stage Renal Disease Network 5, to conduct a Root Cause Analysis (RCA) of the process for arteriovenous fistula (AV fistula) placement. The contract further specified inclusion of patient, physician, dialysis facility and other healthcare environmental factors impacting AV fistula placement. Following completion of the RCA, the contractor was directed to present findings to a Technical Expert Panel (TEP) for review and development of a new FFBI strategic plan.

MARC retained Robert J. Latino, CEO of Reliability Center, Inc. to lead the RCA. To ensure consideration of the various factors and clinical settings, a core team of experts from a variety of backgrounds convened for an intensive two (2) day work session. The core team included:

- Linda Duval, BSN, RN, Network Quality Improvement Director (QID),
- Chester Fox, MD, Primary Care Physician,
- Jerry Jackson, MD, Nephrologist,
- Valerie Riley, RN, BS, FFBI Project Manager, and
- Lawrence Spergel, MD, FACS, Vascular Access Surgeon.

Also assisting with the RCA:

- Nancy Armistead, MPA, Executive Director Network 5,
- Janet Lynch, PhD CPHQ, Deputy Director Network 5 and FFBI Biostatistician,
- Jefferson Rowland, M.Sc., COTR, CMS FFBI Project Officer, and
- Rebecca Morse Steinfield, Consultant, Institute for Healthcare Improvement.

Background

As part of the ESRD Network Statement of Work beginning July 2003, Centers for Medicare & Medicaid Services (CMS), the ESRD Networks and key provider representatives jointly recommended adoption of a National Vascular Access Improvement Initiative (NVAII). The primary goal of this continuous quality improvement (CQI) project was to increase the appropriate use of AV fistula for hemodialysis access and to reach or exceed the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (K-DOQI) practice guidelines of 50% in incident and 40% in prevalent patients. AV fistulas are considered the gold standard of hemodialysis vascular access based on their superior patency, low complication and procedure rates, and subsequent low overall cost. CMS committed to a system-wide improvement project

on vascular access over the course of the three-year ESRD Network contract, starting July 2003, and ending in June 2006. As a result of these efforts, by August of 2005, the national prevalence AV fistula rate was 40%, reaching the prevalence goal 10 months early.

The focus of the original NVAII was to address clinical and organizational improvements that would lead to use of AV fistulas. ESRD Networks, dialysis providers, medical specialists, hospitals and clinics, all share the responsibility for improving dialysis care by increasing appropriate and successful AV fistula placement. The ESRD Networks played a major role in catalyzing change, creating efficient ways to share knowledge and resources, and building strong alliances with the facilities and medical professionals in their regions.

Identification and development of 11 major Change Concepts were provided by a multi-disciplinary working group with representation from the following groups: ESRD Network Executive Directors and Quality Improvement Directors, corporate and independent dialysis providers, nephrologists (including interventional nephrologists), nephrology nurses, vascular surgeons, interventional radiologists, patients, CMS project leaders and quality improvement staff, and the Institute for Healthcare Improvement (IHI). The Change Concept document focuses on changes that can be made immediately, to give all suitable hemodialysis patients the opportunity to receive an AV fistula. Because of the early success, this initiative became known as the Fistula First Breakthrough Initiative (FFBI). As part of the initiative, the FFBI Coalition was formed and is still active today.

The RCA working group identified two main approaches to increasing AV fistula use:

- Clinical and organizational changes that can be adapted and applied locally to improve AV fistula prevalence and success.
- System changes that must be implemented at a national level. These will require national leadership from CMS and should be expected to take longer to accomplish.

Many within the ESRD community pointed out the need for system-level policy changes to encourage more AV fistula placement. These included reimbursement for AV fistulas at a higher rate than AV grafts or catheters, and reimbursement for vessel mapping for new AV fistulas. CMS committed to reviewing these issues carefully for appropriate changes. As a result, in January 2005, a reimbursement policy for vessel mapping was instituted through a new government code (G0365). In addition, until recently there was a financial disincentive for the placement of AV fistulas over AV grafts but the 2009, Relative Value Unit (RVU) adjustments corrected this inequity by a 31% increase over 2008, rates.

The FFBI provided leadership, motivation and support in the form of educational materials, tools to track outcomes, and a clearly outlined process through the 11 Change Concepts to achieve the CMS Clinical Performance Measure (CPM) targets. The FFBI brought vascular access to the

forefront of hemodialysis care, is internationally known and is a household term in most dialysis communities. The FFBI is an exemplary system-wide CQI project that has resulted in a higher number of incident and prevalent AV fistulas.

In the most recent 2006, guideline update K-DOQI recommends a prevalent functional AV fistula placement rate of greater than 65%. In addition, the current CMS goal is to have 66% of prevalent patients using an AV fistula by 2009. As of March 2009, the national average of AV fistulas has increased to 52.0%.

The FFBI contract was awarded to ESRD Network 5, Mid-Atlantic Renal Coalition (MARC), in February 2009. Per the Statement of Work, the FFBI staff is charged with:

- Conducting a thorough analysis of the current process for AV fistula placement;
- Assessing the current strengths, weaknesses and barriers of AV fistula placement;
- Examining the patient, physician, dialysis facility and other healthcare entities that impact AV fistula placement;
- Assess the FFBI's ability to impact the AV fistula rates; and
- Developing and implementing a strategic plan that will move the AV fistula utilization rate to 66%.

Methods

The RCA Team met in Cambridge, Massachusetts at IHI on April 16 - 17, 2009. The structured process completed by the Team included an initial Failure Modes and Effects Analysis (FMEA) to quantify the areas with the greatest opportunity for improvement within the current placement decision-making paths through which patients pass as they move toward and into hemodialysis.

A flow diagram of the decision-making process was prepared in advance of the meeting but refined during the course of discussion. Figure 1 displays the high-level flow diagram the Team used in its FMEA. Included are paths related to decisions that take place in various settings and in conjunction with various participants (i.e., patient, primary care physician, nephrologist, surgeon, interventional nephrologist, interventional radiologist, hospital, and dialysis clinic). Table 1 contains a list of steps through which the FMEA was completed. Full details are available in Appendix A.

Figure 1: Flow Diagram

Decisions in AVF Placement in Hemodialysis Patients

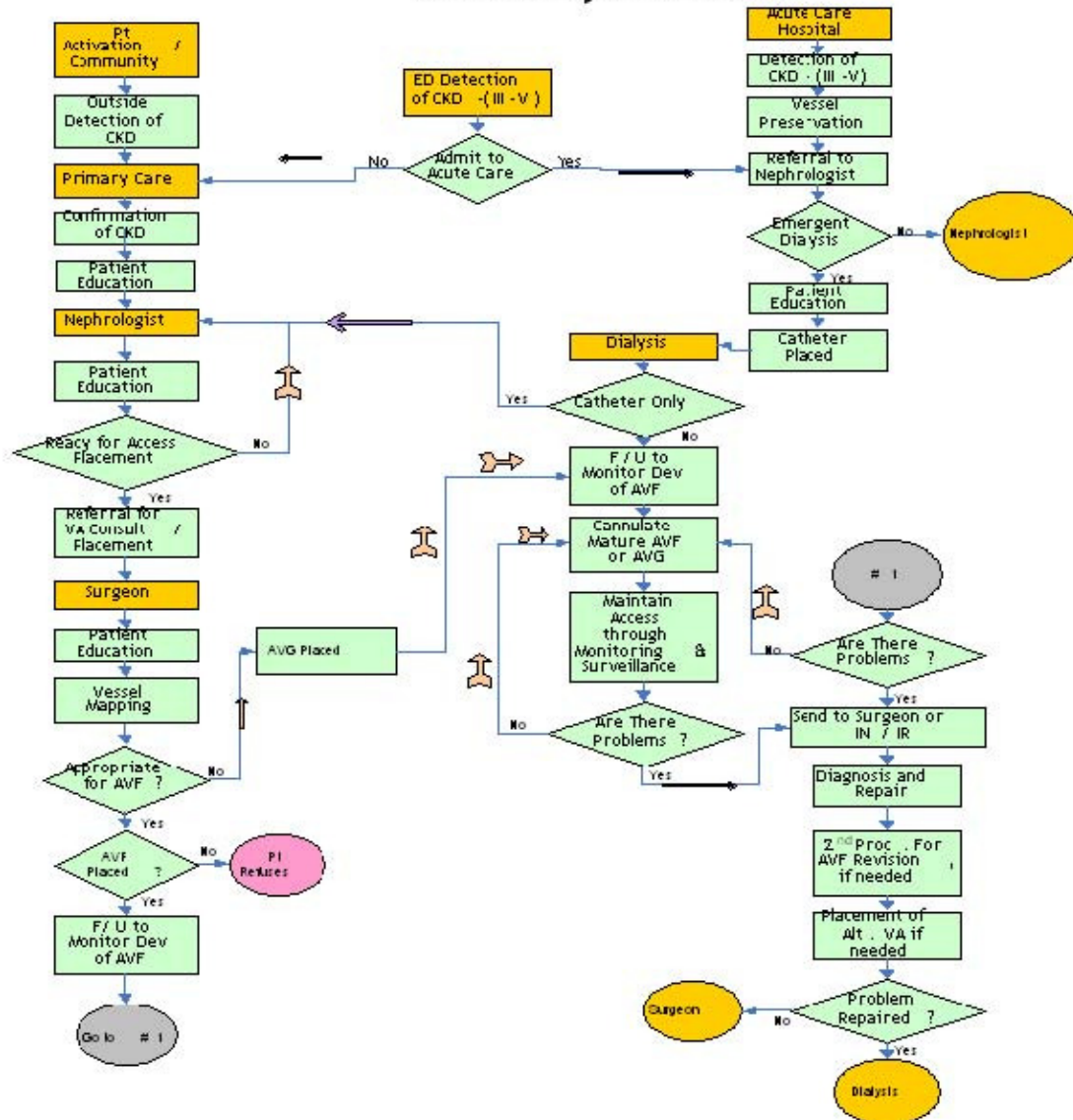


Table 1: Steps in the Failure Modes and Effects Analysis

Number	Step	Description
1	<u>Develop Process Flow Diagram (PFD)</u>	Development of current placement decision-making path for hemodialysis patients.
2	<u>Create Definition of Loss</u>	For this analysis the following definition was utilized, “Any event or condition affecting the placement of an access other than an AV fistula”
3	<u>Establish Weighing Criteria for Probability and Severity</u>	Team members voted on how much of an opportunity (hereinafter referred to as Probability) exists to engage the patient at each step in the process flow, and also when that opportunity presents itself, how much confidence is there that the patient’s decision can be swayed to use the AV fistula (hereinafter referred to as Severity).
4	<u>Weighed Voting by Subject Matter Experts</u>	The RCA Facilitator went through every step in the process flow diagram and polled each Team member for their ranking of Probability and Severity. Straight-line averaging was used to arrive at a Team ranking (total of all votes divided by number of voters).
5	<u>Prioritizing by Rank</u>	When the voting was complete, Probability was multiplied by Severity to arrive at a Rank Prioritization Number (RPN). Once the RPNs were totaled the list was sorted in descending order. The “Significant Few” opportunities were those that represented 80% or greater of the total opportunities identified in the FMEA.
6	<u>Graphically Express Significant Few Listing</u>	The top opportunities for influencing the patient’s decision to use AV fistula in the current process flow were displayed graphically.

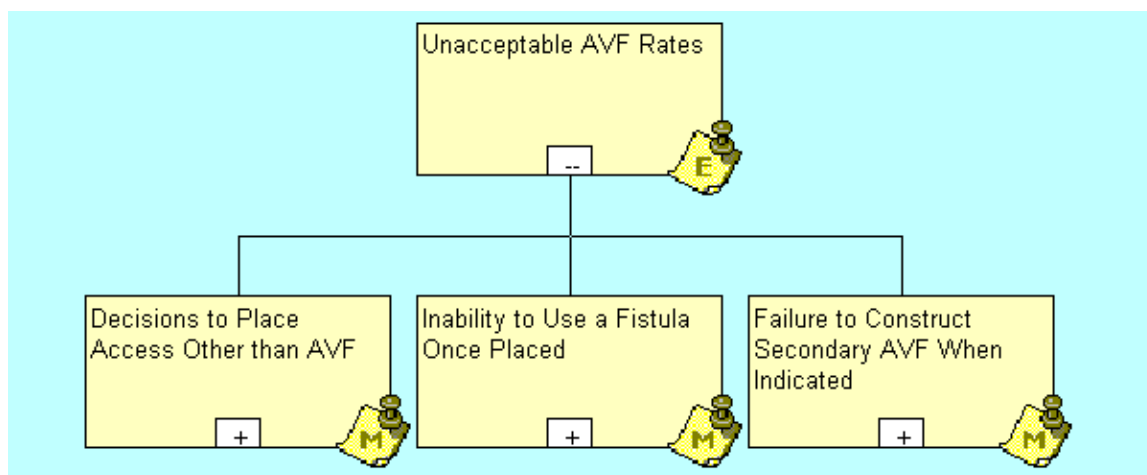
As a result of the FMEA, the Team identified four (4) primary opportunity points. These were the points in the flow diagram at which the Team judged there to be the highest probability of engaging the patient in decision-making related to vascular access and swaying the patient toward the use of an AV fistula. All are under the surgeon primary path and include:

- Determining appropriateness of patient for AV fistula;
- Vessel preservation;
- Follow-up to monitor development of AV fistula; and
- Second procedure for AV fistula revision, if needed.

It was the consensus of the RCA team that while numerous other opportunities were identified during the course of the FMEA, the overwhelming majority would be captured by exploring the above four (4) areas. The RCA team's reasoning was based on an understanding that many identified opportunities are subordinate to these four (4) and, consequently, would be addressed during the course of the comprehensive RCA. An example of the FMEA worksheet can be found in Appendix A.

The RCA drilled down into opportunity areas to identify root causes. The result was a Logic Tree that exceeded 250 blocks, of which 139 were considered root causes. Each block in the Logic Tree represents a hypothesis regarding either “how” or “why” a preceding block was able to occur. The top two (2) levels in the Logic Tree comprise the Event and Modes through which the Event occurs. In this case, the top level Event is an “Unacceptable AV fistula Rate” (i.e., 51.8% in January 2009, vs. the Goal of 66%). The Modes through which this event occurs are understood to include: (1) “Decisions to Place Access Other than AV fistula,” (2) “Inability to Use a Fistula Once Placed,” and (3) “Failure to Construct Secondary AV fistula When Indicated.” See Figure 2 for a picture of the top two (2) levels of the decision tree.

Figure 2: Logic Tree Top Boxes: Event and Modes

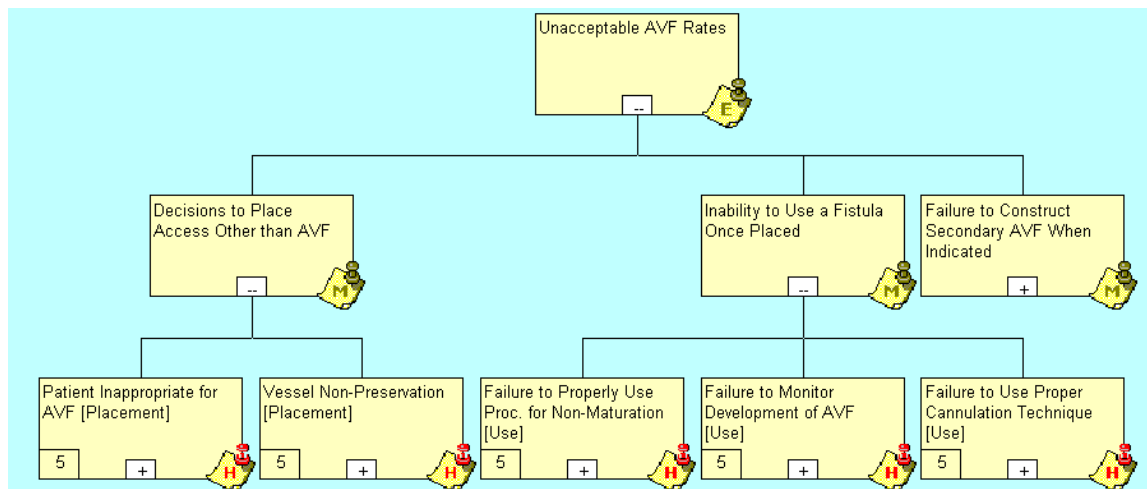


The Logic Tree was fully developed by taking each of the tree Modes and repeatedly asking either “how could” or “why did” this occur? Through this process, the third level on the tree was produced. This level captured the top four (4) opportunities identified in the FMEA, along with other appropriate hypotheses. See Figure 3.

Each logic path was then drilled down extensively (based on cause-and-effect relationships) to uncover the latent root causes or system deficiencies. This process continued until there was RCA team consensus that the identified systemic cause was actionable, meaning that the TEP

could write a recommendation to counter the identified cause and eliminate and/or greatly mitigate the risk of its recurrence. A full, single expression of the 250+ logic tree was prepared with this report. A breakdown of the entire logic tree is provided in Appendix A.

Figure 3: Inclusion of FMEA Top Opportunities



Although the RCA Team identified approximately 139 latent root causes, this does not equate to the need for 139 recommendations. Many identified causes contributed to numerous logic paths affecting decision-making. For instance, “Not Viewed as Cost Effective” was a latent root identified nine (9) times in various different logic paths in the analysis. If the TEP deems it appropriate, perhaps only a single, comprehensive recommendation may address this cause and seek to overcome it.

As it brings forward recommendations, the TEP may also wish to consider the existing Change Concepts developed during the initiation of the FFBI. A list of the Change Concepts, by number, is contained in Table 2, for ease of reference. A fuller description of each is contained in Appendix B. In developing a new strategic plan for the FFBI, a challenge for the TEP will be to consider whether existing Change Concepts are in need of revision, require fuller implementation, or need augmentation with additional relevant Change Concepts.

Table 2: Current Fistula First Breakthrough Initiative Change Concepts

Number	Change Concepts
1	Routine CQI review of vascular access
2	Timely referral to nephrologist
3	Early referral to surgeon for “AV fistula only” evaluation and timely placement
4	Surgeon selection based on best outcomes, willingness, and ability to provide access services
5	Full range of appropriate surgical approaches to AV fistula evaluation and placement
6	Secondary AV fistula placement in patients with AV grafts
7	AV fistula placement in patients with catheters where indicated
8	Cannulation training for AV fistulas
9	Monitoring and maintenance to ensure adequate access function
10	Education to care givers and patients
11	Outcomes feedback to guide practice

Root Cause Analysis Findings

Table 3 below provides a high-level summary of root causes by mode and by issue groupings. Taken together, the 139 root causes contained within these groupings were found by the RCA team to result in a prevalent AV fistula rate that falls short of the 66% goal. All 139 causes are listed in Appendix A.

In excess of 68% of root causes were uncovered in exploration of the Logic Tree branch, “Decision to Place an Access Other than an AV fistula.” Approximately 14% of root causes were identified to explain the second branch of the Logic Tree, “Inability to Use a Fistula Once Placed.” Finally, 18% of root causes explain the third branch, “Failure to Construct Secondary AV fistula when Indicated.”

As depicted earlier in Figure 3, the “Decision to Place an Access Other than an AV fistula” arises because the “Patient is Considered Inappropriate for AV fistula Placement” or because of “Failure to Preserve Vessels.” In turn, the decision with respect to the appropriateness of the patient for AV fistula placement is made either by the “Patient” (i.e., the patient refuses) or by the “Physician” due to “Clinical Contraindications” or “Physician Preference.” Vessel non-preservation results from “Failure to Detect CKD Stages 3-5,” “Failure to Preserve Vessels” when CKD is diagnosed, or “Failure to Refer Patients to the Nephrologist for GFR < 30.” (These five (5) issues constitute a portion of the fourth level of the tree and, along with lower levels are not presented in diagrams here but can be found in Appendix A).

The “Inability to Use a Fistula Once Placed” results from the “Failure to Use Procedures for Non-Maturation,” “Failure to Monitor Development of AV fistula” and “Failure to Use Proper Cannulation Techniques.” These intermediate causes, in turn, were found by the RCA Team to have their own set of root causes. See Appendix A for full expression of the Logic Tree under the mode “Inability to Use a Fistula Once Placed.”

Finally, the third mode, “Failure to Construct Secondary AV fistula When Indicated,” was found to result from “Patient Refusal,” “Nephrologist Resistance,” “Surgeon Resistance” and “Interventionalist Resistance.” These intermediate causes, along with root causes, are also found in the Logic Tree expression in Appendix A.

Table 3: Summary of Identified Root Causes Classified Into Issue Groupings

Modes & Issue Groupings within Modes	Number of Root Causes Related to Groupings	Percent – Overall and Within Groupings *
MODE: DECISION TO PLACE OTHER THAN AV fistula		68.3
Knowledge, Perceptions & Skills	34	24.5
Patient and Family	19	13.7
System	19	13.7
CKD 3-4	13	9.4
Reimbursement	6	4.3
Clinical Decisions	3	2.2
Political Considerations	1	0.7
MODE: INABILITY TO USE ONCE PLACED		13.7
System	12	8.6
Knowledge, Perceptions & Skills	4	2.9
Patient and Family	2	1.4
Reimbursement	1	0.7
MODE: FAILURE TO CONSTRUCT SECONDARY AV fistula		18.0
Knowledge, Perceptions & Skills	16	11.5
Patient and Family	5	3.6
System	3	2.2
Political Consideration	1	0.7

* May not add to 100% due to rounding

Issue Groupings

In preparation for the Technical Expert Panel meeting, the root causes were categorized into six (6) issue groupings as depicted in Table 4 and are discussed below.

- **Knowledge, Perceptions and Skills**

These root causes existed because of a lack of knowledge and/or skills and incorrect perceptions of practitioners. (E.g. Surgeon does not have AV fistula expertise). At a frequency of 34, four (4), and 16 within each of the three (3) modes, most root causes were identified in the category of “Knowledge, Perceptions and Skills.” See Table 3 above. Each root cause within this grouping is listed in Table 4, along with information about the Logic Tree levels above each root cause and the numbers of relevant Change Concepts, developed in the initial phase of the FFBI.

- **Patient and Family**

These root causes existed because of decisions made by patients and/or family members. (E.g. Patient is educated on risk of current access (CVC or AV graft) and is accepting of those risks). At a frequency of 19, two (2), and five (5), “Patient and Family” related issues also characterize root causes in each of the three (3) modes. Individual root causes within the “Patient and Family” grouping are listed in Table 5 below.

- **System**

These root causes existed because of system level decisions and issues. (E.g. Lack of RN education because of pressure to reduce labor cost). At a frequency of 19, 12, and three (3), root causes in the “System” grouping appear under each of the three (3) modes. Table 6 contains a list of these root causes.

- **CKD 3-4**

These root causes existed because of a failure to detect CKD Stages 3-5. (E.g. There is a failure to detect CKD 3-5, because of the lack of an adequate computer flagging system). Root causes categorized as “CKD 3-4” appear 13 times under “Decision to Place Access Other Than AV fistula” and are in Table 8.

- **Reimbursement**

These root causes existed because of reimbursement limitations. (E.g. There is reduced payment for simultaneous procedures, i.e. placement of an AV fistula and a CVC at the same time). Root causes related to “Reimbursement” appear under “Decisions to Place Access Other Than AV fistula” with a frequency of six (6) and one (1) under “Inability to Use Once Placed.” These are in Table 7.

- **Clinical Decision**

These root causes existed because the physician makes a clinical decision based on their knowledge and experience with the patient. (E.g. Physician believes the patient has inadequate vessels for AV fistula). Three (3) root causes characterized as “Clinical Decisions” also appear under “Decisions to Place Access Other Than AV fistula” and are listed in Table 9.

- **Political Consideration**

These root causes existed because of political reasons. (E.g. Nephrologist chooses surgeon based on reasons other than expertise). Root causes that are political in nature appear one (1) time within the Logic Tree under “Decision to Place Access Other Than AV fistula” and one (1) time under “Failure to Construct Secondary AV fistula.” These appear in Table 10.

Logic Tree Levels

As has been previously discussed, the first level on the Logic Tree is the event which is Unacceptable AV fistula rates. This level is followed by the second level of Modes. The third level on the logic tree indicates the top four (4) opportunities identified in the FMEA. They are:

- Determining appropriateness of patient for AV fistula placement;
- Vessel preservation;
- Follow-up to monitor development of AV fistula; and
- Secondary AV fistula, if needed.

Each of these logic paths was drilled down to uncover the latent root causes affecting the placement of an AV fistula. This process continued until there was RCA team consensus that the identified systemic cause was actionable and the TEP could write a recommendation to counter the identified cause and eliminate and/or greatly mitigate the risk of its recurrence.

When reviewing the following Tables you will note that a Higher and Lower Level of the Logic Tree are identified. This was done for ease of following the logic tree during the TEP meeting. By depicting, the levels of the Logic Tree in these tables enabled the TEP members to follow the paths to determine under which branch of the tree the root cause resided. The Logic Tree is further discussed in Appendix A.

FFBI Literature Search

The purpose of a literature search is to identify existing publications most relevant to the subject of interest. To validate the root causes identified during the RCA through literature, the FFBI staff using the PubMed database, performed, a literature search. The search entailed identifying articles relevant to

the root causes published in English, including humans during the period of January 1, 2007 – May 30, 2009.

Identification of articles specific to hemodialysis fistula using the above criteria occurred. Additionally, identification of articles specific to hemodialysis fistula plus each of the following areas also occurred. (E.g. hemodialysis fistula placement)

- Placement
- Complications
- Patient education
- Cannulation training
- Secondary placement
- Failure to use
- Decision not to place
- Failure to monitor
- Surgeon training
- Surgical technique
- Vessel preservation
- Failure to educate
- Train the trainer
- Training patient care technicians
- Failure to educate nurse educator
- Cannulation training for AV fistula
- Effective training for hemodialysis staff
- Interventionalist education for AV fistula
- Educating primary care physicians AV fistula for hemodialysis

A search was also performed for articles specific to Chronic Kidney Disease. Additionally, a search was also performed to identify articles specific to Chronic Kidney Disease plus each of the following areas. (E.g. Chronic Kidney Disease primary care physician)

- Primary care physician
- Referral to nephrologist
- Healthcare decisions for adults without decision-making capacity
- Health literacy

The articles relevant to the root causes were printed, read and the key points of the articles were, documented on worksheets and matched back to the root causes. In the course of reading the articles, a review of citations within these articles occurred to determine if additional relevant articles were available. These articles were also printed, read, documented, and matched back to the root causes. Some of the root causes lacked literature and were deemed RCA expert opinion. All of the articles are documented in the FFBI Bibliography and attached as Appendix C.

Table 4

Root Causes in the Knowledge, Perceptions and Skills Grouping, by Mode, Position in the Logic Tree and Relevant Change Concepts

Ref #	Logic Tree Higher Level	Logic Tree Lower Level	Knowledge, Perceptions & Skills Root Causes (Beneath Levels of Logic Tree Shown on Left)	Relevant Change Concepts
MODE: DECISION TO PLACE ACCESS OTHER THAN AV fistula – 34 (24.5%)				
7	Patient refusal	Education	Educator does not utilize patient education materials that are available	10
8	Patient refusal	Education	Educator is not culturally competent, cannot relate to patient	10
21	Physician decision	Surgeon	Surgeon prefers AVG because of less post operative clinical care is required	5
22	Physician decision	Surgeon	Surgeon believes that reputation is on the line if AV fistula fails	5
23	Physician decision	Surgeon	Surgeon believes that AV fistulas have a negative impact on their schedules	5
24	Physician decision	Surgeon	Surgeon is irritated by calls from other caregivers about AV fistulas	5
25	Physician decision	Surgeon	Surgeon prefers AVG because there are no cannulation issues or problems	5
30	Physician decision	Surgeon	Surgeon does not have AV fistula expertise	4,5
31	Physician decision	Surgeon	Surgeon believes that AV fistula is technically harder to learn than AVG	5
32	Physician decision	Surgeon	Surgeon does not believe that there is enough AV fistula volume to get comfortable with AV fistula creation	5
33	Physician decision	Surgeon	There is no surgical competency oversight	4
34	Physician decision	Surgeon	Surgeon is not competent because AV fistula is technically harder to learn	4,5
35	Physician decision	Surgeon	AV fistula training is not required during residency for general surgery	5,10
36	Physician decision	Surgeon	Training fails to have sufficient volume to get comfortable with AV fistula creation	5,10
37	Physician decision	Surgeon	Surgeons receive biased information on AVG, manufacturers expanding indications beyond clinical appropriateness	5,10
38	Physician decision	Nephrologist	Nephrologist does not want to deal with AV fistula problems	2,3
39	Physician decision	Nephrologist	Nephrologist believes that surgeon does not have experience placing AV fistula	2,3
40	Physician decision	Nephrologist	Nephrologist believes that AV fistulas do not mature because of the lack of surgical experience creating AV fistulas	2,3
41	Physician decision	Nephrologist	Nephrologist believes that AV fistulas do not mature because there is	2,3

Ref #	Logic Tree Higher Level	Logic Tree Lower Level	Knowledge, Perceptions & Skills Root Causes (Beneath Levels of Logic Tree Shown on Left)	Relevant Change Concepts
			inadequate vessel mapping	
42	Physician decision	Nephrologist	Nephrologist believes that AV fistulas do not mature because inappropriate clinical decisions were made due to inadequate vessel selection	2,3
43	Physician decision	Nephrologist	Nephrologist believes that AV fistulas do not mature because there is a failure of monitoring and surveillance	2
45	Physician decision	Nephrologist	Nephrologist lack of education on vascular access for sub groups (obese, elderly, etc.)	2,3
46	Physician decision	Nephrologist	Nephrologist receives biased information on AVG and catheters, manufacturers expanding indications beyond clinical appropriateness	2,8
51	Physician decision	Nephrologist	Nephrologists believes patient has acute renal failure	2
52	Physician decision	Nephrologist	Nephrologist unwilling to talk to prevalent CKD Stage 5 patients about their resistance to AV fistula	2
54	Physician decision	Nephrologist	Nephrologist is not aware of educational materials that are available	2,10
61	Physician decision	Nephrologist	Educator is not culturally competent, cannot relate to patient	10,2
80	Physician decision	Interventionalists	Interventionalist does not perceive advantage of AV fistula due to failure to properly utilize vessel mapping	10,9
81	Physician decision	Interventionalists	Interventionalists failure to follow KDOQI because they do not see the advantage of AV fistula	10,9
82	Physician decision	Interventionalists	Interventionalist does not refer to surgeon as the KDOQI guidelines suggest	10,9
83	Physician decision	Interventionalists	Interventionalist believes that there is an economic disincentive to refer to surgeons if they were to follow the KDOQI guidelines	10,9
84	Physician decision	Interventionalists	Interventionalist lacks knowledge on Fistula First guidelines and does not see the advantage of AV fistula	10,9
85	Physician decision	Interventionalists	Interventionalist does not refer to surgeon as the Fistula First guidelines suggest	10,9
86	Physician decision	Interventionalists	Interventionalist believes that there is an economic disincentive to refer to surgeons if they were to follow Fistula First guidelines	10,9

Ref #	Logic Tree Higher Level	Logic Tree Lower Level	Knowledge, Perceptions & Skills Root Causes (Beneath Levels of Logic Tree Shown on Left)	Relevant Change Concepts
MODE: INABILITY TO USE WHEN PLACED – 4 (2.9%)				
96	Failure to properly use procedure for AV fistula not maturing	Failure to Mature	Fail to use endovascular procedures	9
97	Failure to properly use procedure for AV fistula not maturing	Failure to Mature	Fail to surgically revise when indicated	9
106	Lack of competency in AV fistula cannulation	Cannulation	Educator is not culturally competent and cannot communicate with patient	8
112	Lack of competency in AV fistula cannulation	Cannulation	Educator fails to use available resources	8
MODE: FAILURE TO CONSTRUCT SECONDARY AV fistula – 16 (11.5%)				
120	Nephrologist resistance	Nephrologist	Nephrologist has had previous bad experiences with AV fistula - Mental Barrier	6
121	Nephrologist resistance	Nephrologist	Nephrologist has lack of education related to AV fistula placement	6
123	Nephrologist resistance	Nephrologist	Nephrologist lacks protocol for secondary AV fistula placement	6
124	Nephrologist resistance	Nephrologist	Surgeon not competent to perform AV fistula placement due to lack of surgical volume so nephrologist does not refer for AV fistula placement	6
125	Nephrologist resistance	Nephrologist	Surgeon not competent to perform AV fistula placement due to lack of surgical competency oversight so nephrologist does not refer for AV fistula placement	6
126	Nephrologist resistance	Nephrologist	Education and training limited because of lack of surgical volume so nephrologist does not refer for AV fistula placement	6
127	Nephrologist	Nephrologist	AV fistula education and training not part of General Surgery residency	6

Ref #	Logic Tree Higher Level	Logic Tree Lower Level	Knowledge, Perceptions & Skills Root Causes (Beneath Levels of Logic Tree Shown on Left)	Relevant Change Concepts
	resistance		requirements so nephrologist does not refer for AV fistula placement	
130	Interventionalist resistance	Interventionalist	Interventionalists lack education and training related to Fistula First	6
131	Interventionalist resistance	Interventionalist	Interventionalists lack awareness of protocol for AV fistula placement	6
132	Surgeon resistance	Surgeon	AV fistula education and training not part of General Surgery residency requirements	6
133	Surgeon resistance	Surgeon	Surgeon not competent to perform AV fistula placement due to lack of surgical competency oversight	6
134	Surgeon resistance	Surgeon	Surgeon not competent to perform AV fistula placement due to lack of surgical volume	6
135	Surgeon resistance	Surgeon	Surgeon education and training limited because of lack of surgical volume	6
136	Surgeon resistance	Surgeon	Surgeon lacks awareness of protocol for AV fistula placement	6
137	Surgeon resistance	Surgeon	Surgeon unwilling to apply protocol related to perceived risk of losing functioning graft	6
139	Surgeon resistance	Surgeon	Surgeon unwilling to apply protocol related to complacency and procrastination	6

Table 5

Root Causes in the Patient and Family Grouping, by Mode, Position in the Logic Tree and Relevant Change Concepts

Ref #	Logic Tree Higher Level	Logic Tree Lower Level	Patient and Family Root Causes (Beneath Levels of Logic Tree Shown on Left)	Relevant Change Concepts
MODE: DECISION TO PLACE ACCESS OTHER THAN AV fistula – 19 (13.7%)				
1	Patient refusal	Education	Patient education content is not provided in all languages	10
2	Patient refusal	Education	Patient is not aware of educational materials that are available	10
10	Patient refusal	Education	Patient has inadequate cognitive ability	10
11	Patient refusal	Education	Patient has health literacy issue	10
12	Patient refusal	Fears	Due to lack of patient education, patient is scared of surgery and/or needles	10
13	Patient refusal	Fears	Patient may suffer from mental illness	10
14	Patient refusal	Satisfaction	Patient is educated on risk of current access (catheter or graft) and is accepting of those risks	10
15	Patient refusal	Experience	Patient does not believe that the provider is "pro" AV fistula	2,10
16	Patient refusal	Experience	Patient observes poor AV fistula cannulation techniques	10,8
17	Patient refusal	Experience	Patient perceives the AV fistula to be inconvenient compared to other accesses/ won't give up catheter	10,7
53	Physician decision	Nephrologist	Patient education content is not provided in all languages	10
62	Physician decision	Nephrologist	Patient has inadequate cognitive ability	10,2
63	Physician decision	Nephrologist	Patient has health literacy issue	10,2
64	Physician decision	Nephrologist	Family influences patient not to get AV fistula because of lack of education	10,2
65	Physician decision	Nephrologist	Due to lack of patient education, patient is scared of surgery and/or needles	10,2
66	Physician decision	Nephrologist	Patient fears needles because of comorbid mental illnesses	10,2
67	Physician decision	Nephrologist	Patient is educated on risk of current access (catheter or graft) and is accepting of those risks	10,2
70	Physician decision	Nephrologist	Patient perceives the AV fistula to be inconvenient compared to other accesses	2,10
71	Physician decision	Nephrologist	Patient has proxy who refuses AV fistula	10

Ref #	Logic Tree Higher Level	Logic Tree Lower Level	Patient and Family Root Causes (Beneath Levels of Logic Tree Shown on Left)	Relevant Change Concepts
MODE: INABILITY TO USE WHEN PLACED – 2 (1.4%)				
99	Failure to monitor development of AV fistula	Failure to Monitor	Patient lacks transportation to get to surgeon	9
102	Failure to monitor development of AV fistula	Failure to Monitor	Patient refuses to go to surgeon	9
MODE: FAILURE TO CONSTRUCT SECONDARY AV fistula – 5 (3.6%)				
115	Patient refusal	Patient	Patient educated on risks of CVC and AV graft and is satisfied and accepts risk	6
116	Patient refusal	Patient	Patients medical comorbid medical conditions interfere with placement	6
117	Patient refusal	Patient	Family/support systems influences patient to not have AV fistula placed	6
118	Patient refusal	Patient	Comorbid mental conditions limit patients ability to understand and consent	6
119	Patient refusal	Patient	Patient lacks cognitive ability to make decision and proxy refuses AV fistula placement	6

Table 6

Root Causes in the Grouping of System, by Mode, Position in the Logic Tree and Relevant Change Concepts

Ref #	Logic Tree Higher Level	Logic Tree Lower Level	System Root Causes (Beneath Levels of Logic Tree Shown on Left)	Relevant Change Concepts
MODE: DECISION TO PLACE ACCESS OTHER THAN AV fistula – 19 (13.7%)				
3	Patient refusal	Education	Educator does not have time to educate patient	10
4	Patient refusal	Education	Not seen as cost effective by provider to provide proper supervisory oversight of patient education	10
5	Patient refusal	Education	Establishing a patient education training program is not viewed as cost effective by the provider	10
6	Patient refusal	Education	It's not viewed as cost effective to make an existing patient training program adequate by the provider	10
55	Physician decision	Nephrologist	The Nephrologist believes educator is time pressured, covering a large geographic area in many cases	10
56	Physician decision	Nephrologist	The Nephrologist believes Not seen as cost effective to provide proper supervisory oversight of staff education by the provider	10
57	Physician decision	Nephrologist	The Nephrologist believes establishing a staff education training program is not viewed as cost effective by the provider	10
58	Physician decision	Nephrologist	The Nephrologist believes it is not viewed as cost effective to make an existing staff training program adequate by the provider	10
60	Physician decision	Nephrologist	The Nephrologist believes the educator does not utilize patient education materials that are available	10,2
68	Physician decision	Nephrologist	Patient does not feel that the provider is "pro" AV fistula and reports this to the Nephrologist	also 2
69	Physician decision	Nephrologist	Patient observes poor AV fistula cannulation techniques and reports this to the Nephrologist	2,8
72	Physician decision	Nephrologist	The Nephrologist believes adequate cannulation training process of staff not viewed as cost effective by organization	also 2,8
73	Physician decision	Nephrologist	The Nephrologist believes due to organizational pressure to reduce labor costs, adequate cannulation training not provided	also 2,8
74	Physician decision	Nephrologist	The Nephrologist believes there is organizational pressure for fast	2,7

Ref #	Logic Tree Higher Level	Logic Tree Lower Level	System Root Causes (Beneath Levels of Logic Tree Shown on Left)	Relevant Change Concepts
			turnover, faster to turnover catheter patients then AV fistula patients	
75	Physician decision	Nephrologist	The Nephrologist believes there is organization pressure for fast turnover, faster to turnover catheter patients then AV fistula patients helps reduce labor costs	2,7
76	Physician decision	Nephrologist	The Nephrologist believes there is a lack of RN education because of organizations focus on short term profits	2,10
77	Physician decision	Nephrologist	The Nephrologist believes there is a lack of RN education because of pressure to reduce labor cost	2,10
78	Physician decision	Nephrologist	The Nephrologist believes there is a lack of tech education because of organizations focus on short term profits	2,10
79	Physician decision	Nephrologist	The Nephrologist believes there is a lack of tech education because of pressure to reduce labor costs	2,10
MODE: INABILITY TO USE WHEN PLACED – 12 (8.6%)				
98	Failure to monitor development of AV fistula	Failure to Monitor	Not viewed as cost effective to the organization	9
100	Failure to monitor development of AV fistula	Failure to Monitor	Patient and surgeon scheduling conflicts	9
101	Failure to monitor development of AV fistula	Failure to Monitor	No surgical follow up appointment made by patient	9
103	Lack of competency in AV fistula cannulation	Cannulation	Organizational Focus on Short Term Profits - Productivity Mentality	8
104	Lack of competency in AV fistula cannulation	Cannulation	Organizational Pressure to reduce labor costs	8
105	Lack of competency in AV fistula cannulation	Cannulation	Educator is time pressured, covering a large geographic area and many facilities	8
107	Lack of competency in AV fistula cannulation	Cannulation	No provision for self-cannulation training available	8

Ref #	Logic Tree Higher Level	Logic Tree Lower Level	System Root Causes (Beneath Levels of Logic Tree Shown on Left)	Relevant Change Concepts
108	Lack of competency in AV fistula cannulation	Cannulation	Teaching Skills of Educator lacking due to not being viewed as cost effective	8
109	Lack of competency in AV fistula cannulation	Cannulation	Adequate training process of educator viewed by organization as not cost effective	8
110	Lack of competency in AV fistula cannulation	Cannulation	Establishing a training program for educators is not viewed as cost effective	8
113	Lack of competency in AV fistula cannulation	Cannulation	Lack of organizational ownership and commitment to cannulation credentialing	8
114	Lack of competency in AV fistula cannulation	Cannulation	Lack of organizational oversight to cannulation credentialing	8
<i>MODE: FAILURE TO CONSTRUCT SECONDARY AV fistula- 3 (2.2%)</i>				
122	Nephrologist resistance	Nephrologist	Lack of access to surgeon who performs AV fistula placement	6
128	Nephrologist resistance	Nephrologist	Lack of surgeon in area to perform AV fistula placement	6
138	Surgeon resistance	Surgeon	Surgeon unavailable in area to place AV fistula	6

Table 7

Root Causes in the Grouping of Reimbursement, by Mode, Position in the Logic Tree and Relevant Change Concepts

Ref #	Logic Tree Higher Level	Logic Tree Lower Level	Reimbursement Root Causes (Beneath Levels of Logic Tree Shown on Left)	Relevant Change Concepts
MODE: DECISION TO PLACE ACCESS OTHER THAN AV fistula – 6 (4.3%)				
9	Patient refusal	Education	Reimbursement structure does not support patient education	10
59	Physician decision	Nephrologist	Reimbursement structure does not support staff education	10
26	Physician decision	Surgeon	AV fistula cost more and surgeon is not reimbursed for uninsured patients	5
27	Physician decision	Surgeon	AV fistula takes more surgical time than an AVG but is reimbursed less (<i>Even with the current increase in AV fistula placement, due to the increased time of AV fistula placement the reimbursement is still less than that of an AV graft</i>)	5
28	Physician decision	Surgeon	Surgeon is not paid for post op time and more time is required for AV fistula	5
29	Physician decision	Surgeon	Reduced payment for simultaneous procedures	5
MODE: INABILITY TO USE WHEN PLACED – 1 (0.7%)				
111	Lack of competency in AV fistula cannulation	Cannulation	Scarce human resource available due to current reimbursement structure	8

Table 8

Root Causes in the Grouping of CKD 3-4, by Mode, Position in the Logic Tree and Relevant Change Concepts

Ref #	Logic Tree Higher Level	Logic Tree Lower Level	CKD III – IV Root Causes (Beneath Levels of Logic Tree Shown on Left)	Relevant Change Concepts
MODE: DECISION TO PLACE ACCESS OTHER THAN AV fistula – 13 (9.4%)				
47	Physician decision	Nephrologist	Nephrologist unwilling to talk to CKD stages 3-4 patients about their resistance to AV fistula	2
48	Physician decision	Nephrologist	Nephrologist cannot identify when patient will have to start dialysis, creating a delayed decision by the patient	2,10
49	Physician decision	Nephrologist	Nephrologist cannot convey the importance for AV fistula to the CKD Stage 5 patient	2,10
50	Physician decision	Nephrologist	Nephrologist has to initiate patient on dialysis (urgent) before the patient has made a decision to get an AV fistula	2
87	Vessel Non-preservation		Failure to educate non-nephrologist on acute care setting on vessel preservation with detection of CKD 3-5	10,2
88	Vessel Non-preservation		Failure to educate non-nephrologist in outpatient setting on vessel preservation with detection of CKD 3-5	10,2
89	Vessel Non-preservation		The lack of an adequate computer flagging system there is a failure to detect CKD 3-5	1,10
90	Vessel Non-preservation		Inadequate use of discharge planning there is a failure to detect CKD 3-5	1,10
91	Vessel Non-preservation		Failure to educate patients on vessel preservation	10
92	Vessel Non-preservation		Over utilization of PICC lines	1,10
93	Vessel Non-preservation		Failure to educate PCPs on vascular access/vessel preservation	1,2,10
94	Vessel Non-preservation		Failure to influence on vascular access/vessel preservation	1,2,10
95	Vessel Non-preservation		Failure for nephrology to approve all PICC lines with GFR < 45	2,10

Table 9

Root Causes in the Grouping of Clinical Decisions, by Mode, Position in the Logic Tree and Relevant Change Concepts

Ref #	Logic Tree Higher Level	Logic Tree Lower Level	Clinical Decisions Root Causes (Beneath Levels of Logic Tree Shown on Left)	Relevant Change Concepts
<i>MODE: DECISION TO PLACE ACCESS OTHER THAN AV fistula – 3 (2.2%)</i>				
18	Physician decision	Clinical Contraindication	Physician believes patient has short life expectancy	2
19	Physician decision	Clinical Contraindication	Physician believes the patient has inadequate vessels for AV fistula	2,3
20	Physician decision	Clinical Contraindication	Physician believes vascular access induced ischemia prevents the use of an AV fistula	2,3

Table 10

Root Causes in the Grouping of Political Consideration, by Mode, Position in the Logic Tree and Relevant Change Concepts

Ref #	Logic Tree Higher Level	Logic Tree Lower Level	Political Consideration Root Causes (Beneath Levels of Logic Tree Shown on Left)	Relevant Change Concepts
<i>MODE: DECISION TO PLACE ACCESS OTHER THAN AV fistula – 1 (0.7%)</i>				
44	Physician decision	Nephrologist	Nephrologist chooses surgeon based on reasons other than expertise	4
<i>MODE: FAILURE TO CONSTRUCT SECONDARY AV fistula – 1 (0.7%)</i>				
129	Interventionalist resistance	Interventionalist	Inability to overcome business self interest	6

Summary

The RCA Team utilized a disciplined approach to uncover the systemic root causes associated with why there the AV fistula utilization rates across the country were not higher. A concerted effort was made to drill down to the core of the decision-making processes of both patients and caregivers. Many causes uncovered in the analysis involved some sensitive issues that will require an extra degree of diplomacy and fortitude in recommendation writing. Some solutions will have to tackle current restraining paradigms and realities regarding the current business infrastructure of clinical systems. Business realities such as current reimbursement rates and incentives for placement alternatives as well as paradigms about the cost effectiveness of training of patients and caregivers are at the core of why many today decide not to use AV fistula for their access placement of choice. It is the consensus of the RCA Team that by addressing these deeply rooted and sensitive issues uncovered by the analysis, the stretch goal of the FFBI of attaining an AV fistula utilization rate of 66% nationally is not only possible, but also likely to exceed the goal.

Next Steps

The RCA report will be provided to a TEP, which is made up of experts from the renal community. There is representation from nephrologists, interventionalists, vascular surgeons, Network Executive Directors and Quality Improvement Directors, Quality Improvement Organizations, insurers, Large Dialysis Organizations, educators and consumers. In addition, there will be representation from CMS, IHI and Reliability Center, Inc. A complete list of TEP members can be found in Appendix D. The TEP will convene in Phoenix, Arizona on June 4 – 5, 2009. The TEP is charged with development of interventional strategies that are reasonable and sustainable to address identified root causes in order to move the national AV fistula utilization rate to 66% in prevalent hemodialysis patients.

Appendix A
Fistula First Breakthrough Initiative (FFBI)
PROACT Root Cause Analysis Report

Message from Root Cause Analysis Facilitator

The Root Cause Analysis (RCA) Core Team of Subject Matter Experts (SME) from varied backgrounds and perspectives utilized a disciplined approach to uncover the systemic root causes associated with why there was not a higher AV fistula utilization rate across the country.

This report will allow a detailed review of the analytical processes involved and the associated outcomes. A concerted effort was made to drill down to the core of the decision-making processes of both patients and caregivers.

Many causes uncovered in the analysis involved some very sensitive issues that will require an extra degree of diplomacy and fortitude in recommendation writing. Some solutions will have to tackle current restraining paradigms and realities regarding the current business infrastructure of clinical systems. Business realities such as current reimbursement rates and incentives for placement alternatives as well as paradigms about the cost effectiveness of training of patients and caregivers are at the core of why many today decide not to use AV fistula for their access placement of choice.

In general, current education curriculums do not adequately encourage the use of AV fistula. This is evidenced by the fact that most clinicians are not taught the advantages of AV fistula over other placement alternatives. Nor are they provided the knowledge (classroom training) and skill (opportunities to apply) involved with proper surgical techniques in how to perform such procedures.

The Team feels strongly that by not tackling such deeply ingrained paradigms, progress towards the stated goal will be gradual at best.

It is the consensus of the RCA Team that by addressing these very deeply rooted and sensitive issues uncovered by the analysis, the stretch goal of the Fistula First Breakthrough Initiative (FFBI) of attaining an AV fistula utilization rate of 66% nationally is not only possible, but also likely to be exceeded.

RCA Lead Facilitator

Robert J. Latino

Root Cause Analysis (RCA) Core Team Scope of Work (SOW) Review

The Core RCA Team will conduct a thorough Root Cause Analysis of the process for ArterioVenous Fistula (AV fistula) placement. The RCA will assess the current strengths, weaknesses and barriers of AV fistula placement and the ability of the Fistula First Breakthrough Initiative (FFBI) to impact the AV fistula placement rate such that it will achieve CMS goals.

Table 1a
FFBI RCA Core Team Member Listing

Position	Member	Description
RCA Team Member <i>Vascular Surgery</i>	Lawrence Spergel, MD, FACS Vascular Surgeon Dialysis Management Medical Group 1402 Post Street, Suite C San Francisco, California 94109 415-440-8267 vampdoc@aol.com	Dr. Spergel has specialized in dialysis access surgery and management since 1975. He is Director of the Dialysis Management Medical Group and a member of the clinical faculty of the University of California, San Francisco. Dr. Spergel has been an integral part of the Fistula First project since its inception in 2003. He served as Chair of the original working group, which developed the Change Concepts that enabled Networks to successfully implement the FFBI and has served as the Clinical Chair for the project. He lectures and publishes regularly on vascular access issues.
RCA Team Member <i>Interventional Nephrology</i>	Jerry Jackson, MD Nephrology Associates 817 Princeton Avenue, SW Birmingham, Alabama 35211 205-970-8870 jjackson@nephrologypc.com	Dr. Jackson is Medical Director of the Nephrology Vascular Lab and works as an interventional nephrologist (while continuing to practice nephrology). He is a member of the American College of Physicians, the American Society of Nephrology, and the American Quality Society. He is certified through the Institute for Healthcare Improvement as an Improvement Advisor.
RCA Team Member <i>Dialysis Nurse & Network Quality Improvement Director</i>	Linda Duval, BSN, RN Quality Improvement Director ESRD Network 13 4200 Perimeter Center Drive, Suite 102 Oklahoma City, Oklahoma 73112 405-942-6000 lduval@nw13.esrd.net	Ms. Duval is the Quality Improvement Director for ESRD Network 13. She is responsible for the development, implementation, evaluation and management of quality improvement projects and other related quality improvement activities such as the collection of data on the Clinical Performance Measures. Ms. Duval has been actively involved in the Fistula First Initiative since inception in 2003.
RCA Team Member <i>Primary Care Physician</i>	Chester Fox MD 1315 Jefferson Ave Jefferson Family Medicine Buffalo, New York 14208 716-744-0487 chetfox@gmail.com	Dr. Fox is the author of "Primary Care Physicians' Knowledge and Practice Patterns in the Treatment of Chronic Kidney Disease: An Upstate New York Practice-based Research Network (UNYNET) Study." He has worked with ESRD Network of New England on Fistula First activities.

RCA Team Member	Valerie Riley, RN, BS Project Manager Fistula First ESRD Network 5 1527 Huguenot Road Midlothian, VA 23113 804-794-5824 vriley@nw5.esrd.net	Ms. Riley is a healthcare professional with over 20 years experience working in the ESRD industry who has a strong focus on Clinical Operations and Quality Improvement processes. Prior to joining the FFBI project, she worked with a Large Dialysis Organization managing a 35-station, 200+ patient dialysis facility to successfully meet the Clinical, Operational and Financial goals of the organization.
Dialysis Nurse & FFBI Project Manager		

Overall RCA Team Charter

To identify the root causes of the Significant Few Reasons for decision-makers to choose access placement other than AV fistula for hemodialysis. This includes identifying deficiencies in, or lack of, management systems. These root causes will be communicated to TEP for rapid resolution.

Formal RCA Team Meeting(s)

Date(s): April 16 – 17, 2009

Location: Cambridge, MA, IHI Conference Facilities

Failure Modes and Effects Analysis Detailed Description

FMEA Process

The Failure Modes and Effects Analysis (FMEA) tool was originally designed to detect flaws, unacceptable risks, in the new design of equipment such as aircraft. Over the decades, this tool has been widely modified for application on existing systems. The RCA Team applied such a variation of the FMEA tool to assist in identifying the greatest opportunities in the current placement decision-making paths available to hemodialysis patients.

The following steps comprised the prep and analysis work for this modified FMEA approach:

Step 1: Develop Process Flow Diagram (PFD). Development of current placement decision-making path for hemodialysis patients (See Exhibit 1)

Step 2: Create Definition of Loss. For this analysis the following definition was utilized, “Any event or condition affecting the placement of an access other than an AV fistula”

Step 3: Establish Weighing Criteria for Probability and Severity. Team members will vote on how much of an opportunity (hereinafter referred to as Probability) exists to engage the patient at each step in the process flow, and also when that opportunity presents itself, how much confidence is there that the patient’s decision can be swayed to use the AV fistula (hereinafter referred to as Severity). The full weighing scales used in the analysis are located in Exhibit 2.

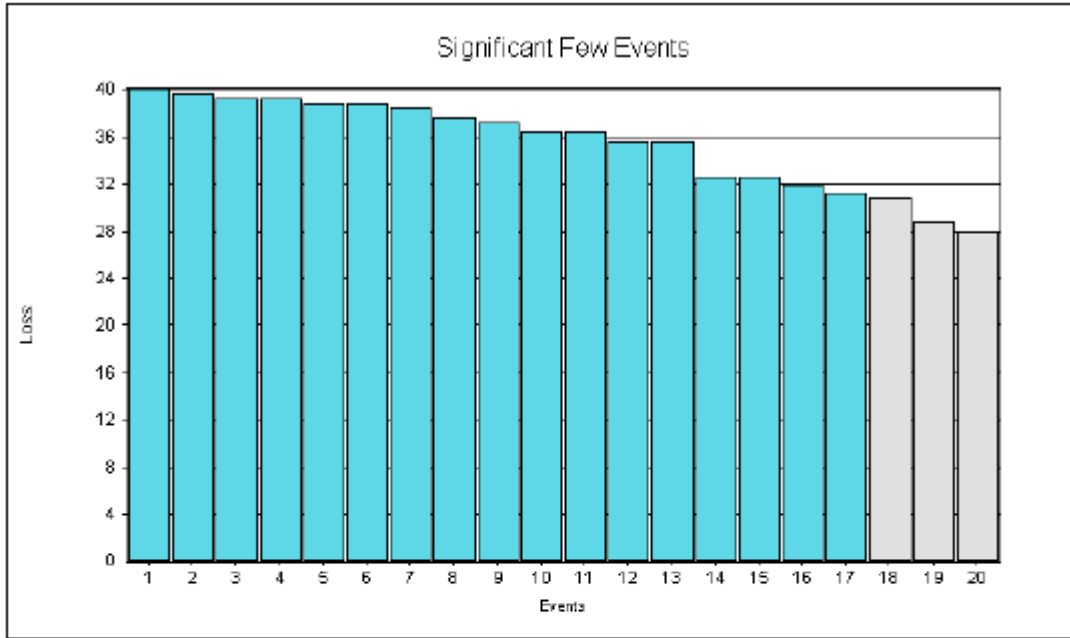
Step 4: Voting by Subject Matter Experts. The RCA Facilitator went through every step in the process flow diagram and polled Team members for their ranking of Probability and Severity. These individual rankings can be viewed in Exhibit 3, Page 46. Straight line averaging was used to arrive at a Team ranking (total of all votes divided by number of voters). It should be noted that several steps in the process flow were decision paths or steps in which made them not appropriate for voting. Under these conditions, they received a default of “1”.

Step 5: Prioritizing by Rank. When the voting is complete, Probability is multiplied by Severity to arrive at a Rank Prioritization Number (RPN). Once the RPN’s are totaled the list can be sorted in descending order. The “Significant Few” opportunities are those that represent 80% or greater of the total opportunities identified in the FMEA.

Step 6: Graphically Express Significant Few Listing. The following chart represents the top four (4) opportunities for influencing the patient’s decision to use AV fistula in the current process flow. For a full listing of all opportunities and their rankings see Exhibit 5a.

Figure 1a: FMEA: Significant Few Chart (Refer to page 59 for full list of events)

The Event numbers at the bottom of the graph below represent the significant few events that occur in descending order (i.e. highest to lowest). The Loss numbers on the side of the graph below represent the total losses for each of the significant few events.



ID	Event	Mode	RPN
1	Decision to Use Access Placement Other than AVF	Second Proc. for AVF Revision if Needed	40
2	Decision to Use Access Placement Other than AVF	Appropriate for AVF (?)	39.6
3	Decision to Use Access Placement Other than AVF	F/U to Monitor Dev. of AVF	39.2
4	Decision to Use Access Placement	Vessel Preservation	39.2

Step 7: FMEA Conclusions. Excluding the eight (8) steps in the process that were not measurable either because they were either not applicable or they were steps without any opportunity to engage patient about placement alternatives, 21 steps were weighed by each of the RCA Team members. The total weight for all weighed steps was 709.92. Sixteen of the weighed 21 steps represented 76.2% (567.94) of the opportunity points in the process to influence patient decisions about placement alternatives.

The top four (4) identified opportunity points were all under the Surgeon primary path as follows:

1. 2nd Procedure for AV fistula Revision if Needed	40.0
2. Decision Point: Was Patient Appropriate for AV fistula	39.6
3. Follow Up to Monitor Development of AV fistula	39.2
4. Vessel Preservation	39.2

Collectively these four (4) top opportunities totaled 158 or 22.3% (158/709.92) of the total of all opportunity points.

Step 8: FMEA Recommendations. It was consensus of the RCA Team that while numerous opportunities were identified, that the top four (4) would capture the overwhelming majority of the Significant Few. The reasoning for this was based on the belief that many opportunities were subordinate to these top four (4) and that in the course of the comprehensive RCA, they would be indirectly addressed. Therefore it was recommended, and carried out that these four (4) top opportunities would be subjected to the scrutiny of the RCA drill down process to better understand the details of the decision-making processes involved.

Step 9: Issue FMEA Report. A final report was issued based on the aggregation of the above information collected during the course of the analysis. To view the entire FMEA report, please refer to Exhibit 5a.

Root Cause Analysis (RCA) Detailed Process Description

The RCA Team adopted the use of the PROACT[®] Root Cause Analysis methodology. This methodology adheres to the following investigative process steps:

1. **P**reserving Failure Data
2. **O**rdering the Analysis Team
3. **A**nalyzing the Data
4. **C**ommunicating Findings and Recommendations
5. **T**racking for Bottom-Line Results

Preserving Failure Data – The first step in any investigation is to develop a data collection strategy to aid in the efficiency of analyzing the data to draw conclusions. In this particular analysis, because of the limited time the Team was together, data collection strategy was discussed at length to support hypotheses arising from debates. However, the actual collection phase of the literature took place after the Team meeting after all causes were identified. This simply meant that the actual validation of the causes took place post-RCA due to the constraints (i.e. – time and proximity) of the project scope of work. In the end, all root causes were validated via the means stated on the Verification Log (See Exhibit 6a).

Ordering the Analysis Team – As stated in the Executive Summary, the RCA Team member listing demonstrates the intent of alleviating bias of the Team towards any pre-determined outcomes. The makeup of the Team allowed varying perspectives from professionals who deal directly with the patients with regards to chronic kidney disease and the patient's options. The RCA Lead Facilitator was an expert in the discipline of the RCA process and not a clinician. The facilitator's role was to extract the knowledge of the Subject Matter Experts (SME) on the Team in an unbiased and substantiated fashion.

Analyzing the Data – The RCA Team spent their entire time together discussing, in a very methodical and disciplined manner, why patients and medical professionals opt for placement alternatives other than AV fistula. The analysis started with looking at the top opportunities to influence the patient's decision drafted from the FMEA results.

The aggregation of these "thoughts" from the Subject Matter Experts (SME's) were graphically represented in the form of a Logic Tree. Logic Tree's start with facts about an undesirable outcome and then work backwards in time by hypothesizing "how could" something have occurred. This expression of backwards logic demonstrates cause-and-effect relationships from level-to-level. As a result, this methodology shows a direct correlation from deficient organizational systems to poor decision-making to undesirable outcomes.

Unlike categorical approaches which typically utilize brainstorming to come up with disconnected ideas under a cause category umbrella (i.e. – management, manpower, materials,

etc.), cause-and-effect approaches are able to demonstrate direct correlations from bad system to bad outcomes.

While there is no universally accepted definition of Root Cause Analysis (RCA), one commonality of most approaches is that RCA's are conducted on individual events as opposed to a population of events. This RCA was unique in that the goal was to look across a spectrum of outcomes around the country and to use the SME's experience and expertise to identify the most common causes of those outcomes. Essentially this project was equivalent to what is called a Common Cause Analysis (CCA). CCA is used when reviewing a series of related outcomes. To accommodate the large scope of this project we employed the FMEA tool to identify the greatest opportunities to focus on in the limited time the Team had together. This proved to be a very productive approach based on the results of the combined analyses.

Hypothesis Validation

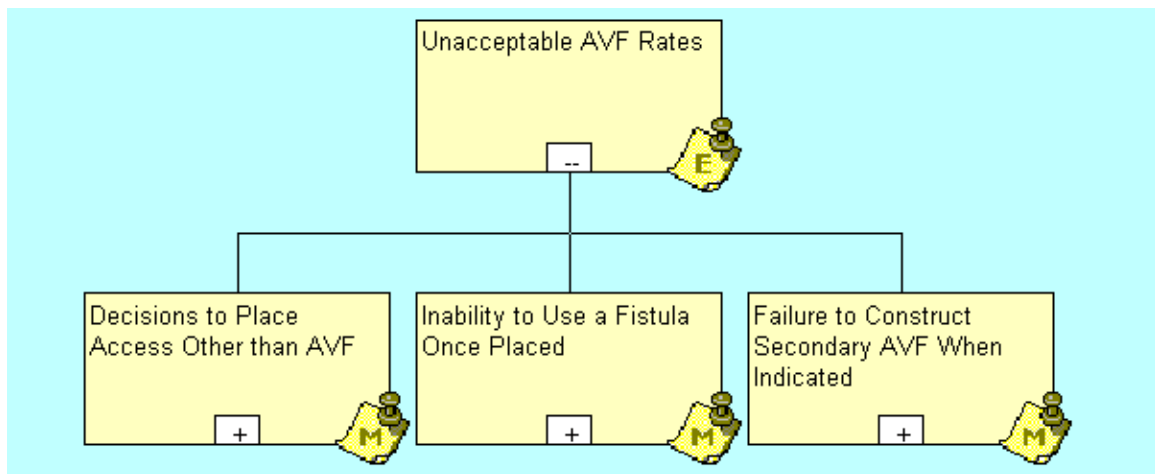
The Logic Tree developed by the RCA exceeded 250 blocks. Each block represented a hypothesis regarding either "how" or "why" a preceding block was able to occur. Each identified latent cause was validated with the best available data known to the Subject Matter Experts (SME) at the time of the analysis. This evidence took the form of 1) hard data (science), 2) literature searches (benchmarks) and 3) direct observation by RCA Team members. Every effort was taken to remove "hearsay" (third party opinion) as a sole, valid form of evidence. (See Exhibit 6). *Note: The Mid-Atlantic Renal Coalition (MARC) took the lead in coordinating the completion of the Verification Log and this document was a work-in-progress at the time of the release of this draft report. (See Exhibit 6a).*

Logic Tree Development

The top box of the Logic Tree comprises the Event and the Modes. A requirement is that both of these levels are factual and not include supposition or assumption. The Event is characterized as the ultimate consequence. In this case the Event is in line with the SOW and is characterized as "Unacceptable AV fistula Rates" (51.8% in January/09 as opposed to the desired rate of 66%). The established Modes were 1) *Decisions to Place Access Other than AV fistula*, 2) *Inability to Use a Fistula Once Placed* and 3) *Failure to Construct Secondary AV fistula When Indicated*.

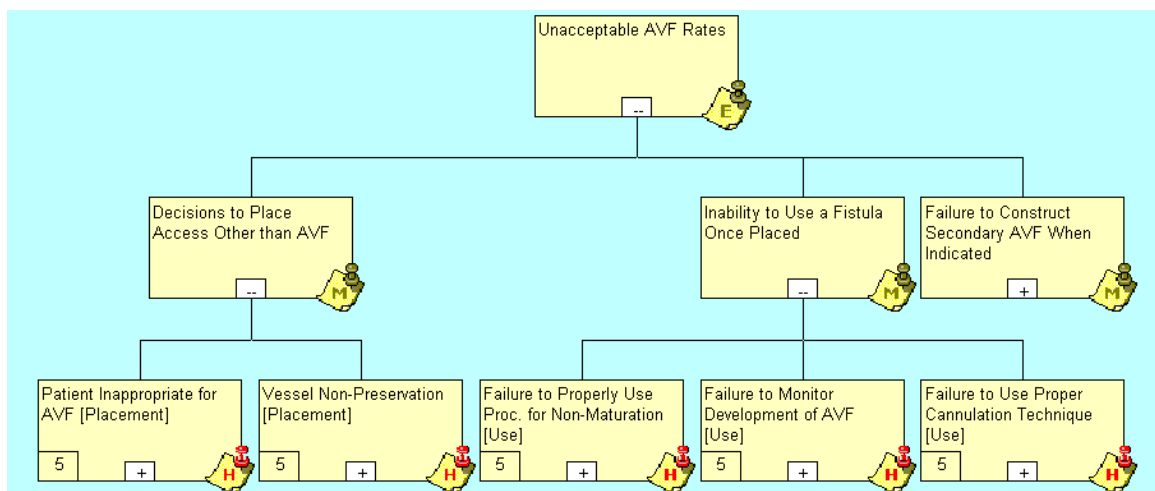
In this case the RCA team established the following for its Event and Modes:

Figure 2a: Logic Tree Top Box: Event and Modes



From this point down, the question was repeatedly asked as either “how could” or “why did” this occur? The next level on this Logic Tree represented the top four (4) opportunities identified in the FMEA previously described. These were inserted at this point, along with other appropriate hypotheses. This insertion of top opportunities allowed each logic path to be drilled down extensively (based on cause-and-effect relationships) to uncover the latent root causes or system deficiencies.

Figure 3a: Inclusion of FMEA Top Opportunities



A full, single expression of the 250+ logic tree was provided with this report. A breakdown of the entire logic tree is also provided on standard size 8-1/2” x 11” using page connectors in Exhibit 7a.

Confidence Factors

Confidence factors are the application of weights to measure the confidence in the evidence used to support each hypotheses and/or cause. These weights are a subjective measure of strength of evidence by the Subject Matter Experts (SME). The following weighing scale was used for Confidence Factors:

5 = Absolutely True

4 = High Probability of Being True

3 = Moderate Probability of Being True

2 = Low Probability of Being True

1 = Very Low Probability of Being True

0 = Absolutely Not True

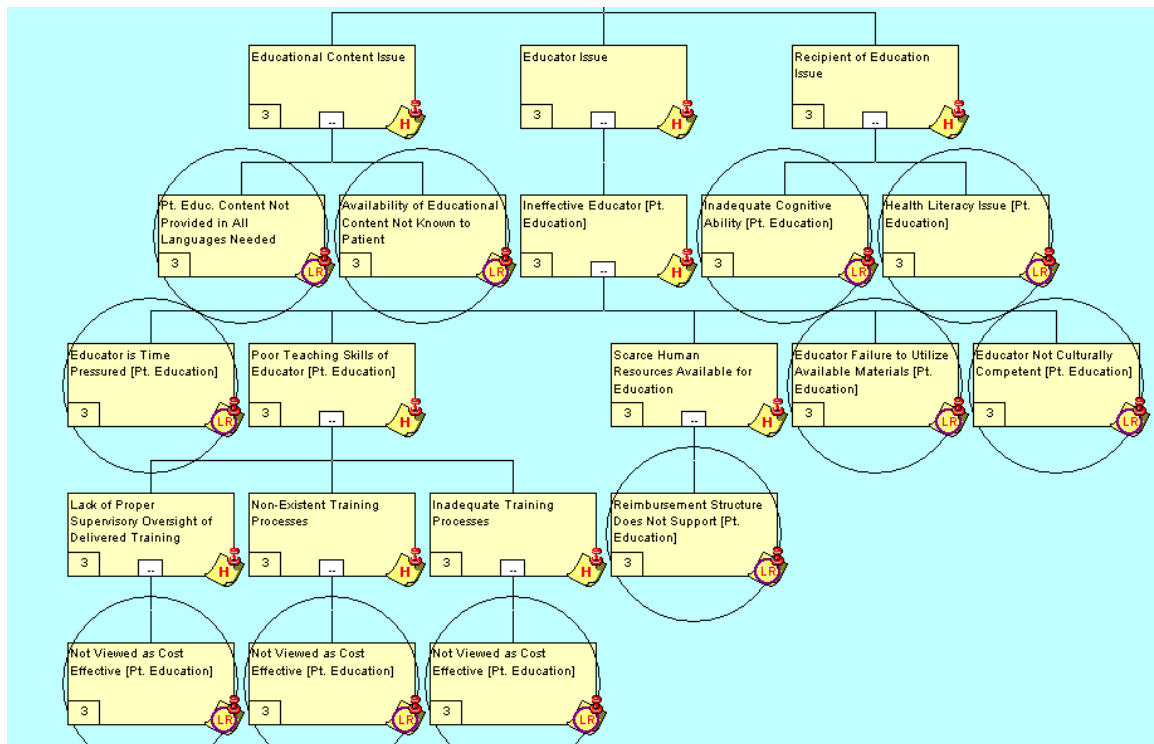
Drilling Down the Logic Tree

Each node was continuously drilled down until there was Team consensus the identified systemic cause was actionable. “Actionable” meaning the Technical Expert Panel (TEP) could write a recommendation to counter the identified cause and eliminate and/or greatly mitigate the risk of its recurrence. All causes identified in this analysis were labeled as Latent Root Causes (LR) so as not to add complexity to the interpretation of the Logic Tree. While the Team could have easily labeled additional nodes in the Logic Tree as Human Roots (HR) or Physical Roots (PR), there was no perceived value in doing so. The reason for this is if the systemic deficiencies are corrected (via the TEP recommendations), then this will improve decision-making and therefore encourage the new desired behavior to be exhibited. When proper decisions are made, then there will no longer be an error chain leading to undesirable outcomes. The chains will have been broken by correcting the organizational systems affecting decision-making.

The following is a representative sample of how a certain logic path (i.e. – Patient Education) during the Team meeting resulted in the identification of numerous Latent Root Causes. When the “system” of Patient Education was being explored, it was broken down into its major, manageable components; educational content, educator and recipient (patient).

Please note that “+” and “-“in the blocks simply represent the ability to expand and collapse levels of the tree for viewing purposes. A “+” in a parent block indicates the presence of child blocks beneath.

Figure 4a: Logic Tree: Representative Logic Path – Patient Education



Communicating Findings and Recommendations

The RCA Team identified approximately 139 Latent Root Causes. However, this does not equate to the need for at least 139 recommendations. Many identified causes contributed to numerous logic paths affecting decision-making. For instance, “Not Viewed as Cost Effective” was a Latent Root identified nine (9) times in various different logic paths in the analysis (See Business Related Causes). If TEP deems it appropriate, perhaps only a single, comprehensive recommendation may address this cause and seek to overcome it. The following is a high level breakdown of identified RCA causes, their cause groupings and sub-categories and their frequency of identification in the RCA. For a detailed listing of all identified causes, groupings and sub-categories, please refer to Exhibit 8a.

Table 2a: RCA: Breakdown of Detailed Cause Groupings

Modes & Issue Groupings within Modes	Number of Root Causes Related to Groupings	Percent – Overall and Within Groupings *
MODE: DECISION TO PLACE OTHER THAN AV fistula		68.3
Knowledge, Perceptions & Skills	34	24.5
Patient and Family	19	13.7
System	19	13.7
CKD 3-4	13	9.4
Reimbursement	6	4.3
Clinical Decisions	3	2.2
Political Considerations	1	0.7
MODE: INABILITY TO USE ONCE PLACED		13.7
System	12	8.6
Knowledge, Perceptions & Skills	4	2.9
Patient and Family	2	1.4
Reimbursement	1	0.7
MODE: FAILURE TO CONSTRUCT SECONDARY AV fistula		18.0
Knowledge, Perceptions & Skills	16	11.5
Patient and Family	5	3.6
System	3	2.2
Political Consideration	1	0.7

Tracking for Bottom-Line Results

While an important step in the overall PROACT® Root Cause Analysis process, this responsibility will be that of the FFBI contractor. The TEP is responsible for developing recommendations for the root causes identified by the RCA Team. Determining metrics to track bottom-line impact of those recommendations can only be done after the recommendations have been developed.

Exhibit 1a

Decisions in AV fistula Placement in Hemodialysis Patients Process Flow Diagram

Decisions in AVF Placement in Hemodialysis Patients

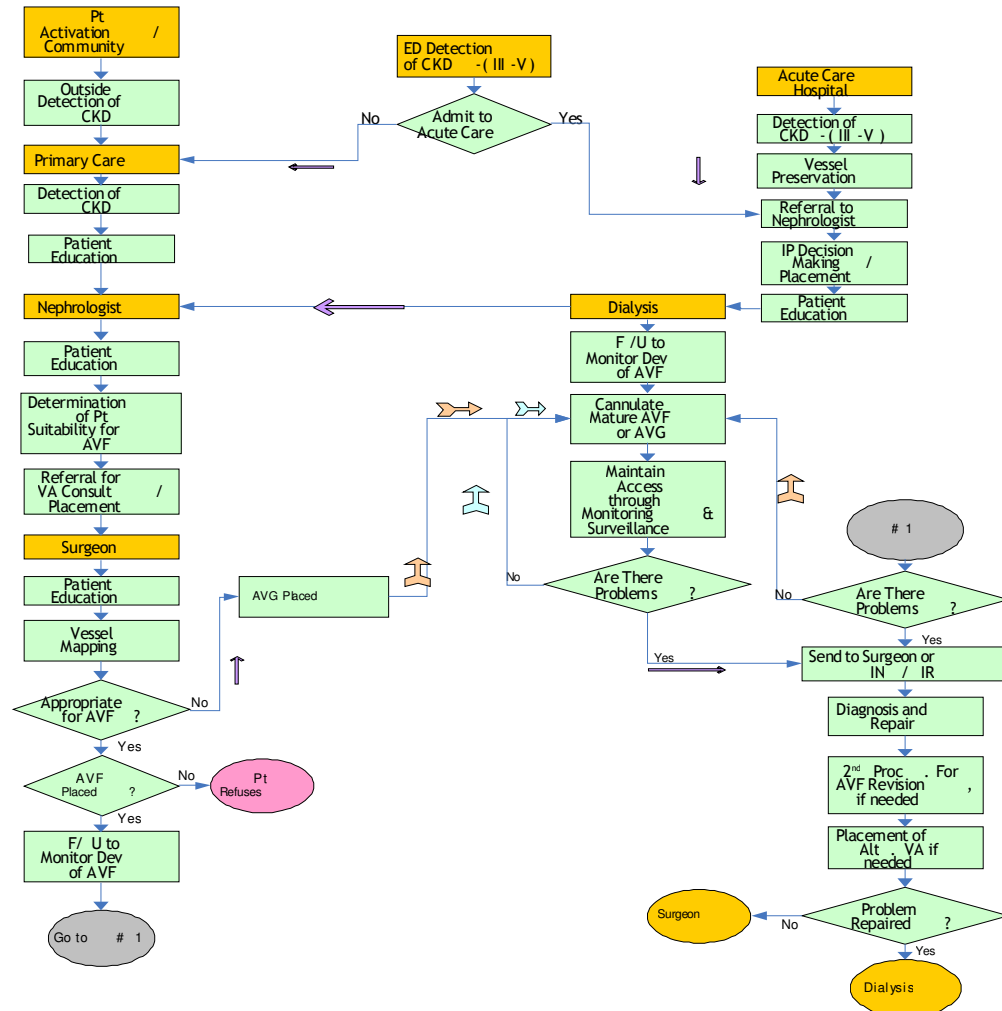


Exhibit 2a

Probability and Severity Weighing Scales

PROBABILITY CRITERIA

Opportunity Points in the Process to Affect AV Decision

- **Frequent (4)**
 - High likelihood to affect AV placement decision at this point in process (75% >)
- **Occasional (3)**
 - Probably will affect AV placement decision at this point in process (50% - 74%)
- **Uncommon (2)**
 - Possibly will affect AV placement decision at this point in process (25% - 49%)
- **Remote (1)**
 - Unlikely to affect AV placement decision at this point in process (1% - 24%)

SEVERITY/IMPACT CRITERIA

The Ability to Sway Decision During Opportunity

- **Definitive Influence (10)**
 - Decision point in process influences decision to use placement of an access other than an AV fistula
- **High Influence (7)**
 - Decision point in process influences decision to use placement of an access other than an AV fistula
- **Moderate Influence (4)**
 - Decision point in process influences decision to be inconclusive about access placement
- **Minor Influence (1)**
 - Decision point in process does not greatly influence decision about access placement

Exhibit 3a

FMEA Team Member Voting Details

Mid-Atlantic Renal Coalition FFBI RCA - Team Meeting

April 16 - 17, 2009

Boston, MA

Legend:

P =
Probability

S = Severity
(Impact)

S = Severity (Impact)			Team Member Individual Rankings														
			Dr. Lawrence Spergel		Dr. Jerry Jackson		Ms. Linda Duval		Dr. Chester Fox		Ms. Val Riley		Consensus Team Ranking		Total RPN		
Sub-System	Event	Mode	P	S	P	S	P	S	P	S	P	S	P	S			
Pt. Activation/ Community	Decision to Use Access Placement Other Than AV fistula	Outside Detection of CKD	Not Applicable Step for Weighing														
Primary Care	Decision to Use Access Placement Other Than AV fistula	Confirmation of CKD	4.0	7.0	4.0	7.0	4.0	7.0	4.0	7.0	4.0	7.0	4.0	7.0	28.00		
Primary Care	Decision to Use Access Placement Other Than AV fistula	Patient Education	4.0	7.0	3.0	8.0	3.0	7.0	3.0	9.0	3.0	6.0	3.2	7.4	23.68		
Nephrology	Decision to Use Access Placement Other Than AV fistula	Patient Education	4.0	9.0	4.0	9.0	4.0	9.0	4.0	9.5	4.0	8.0	4.0	8.9	35.60		

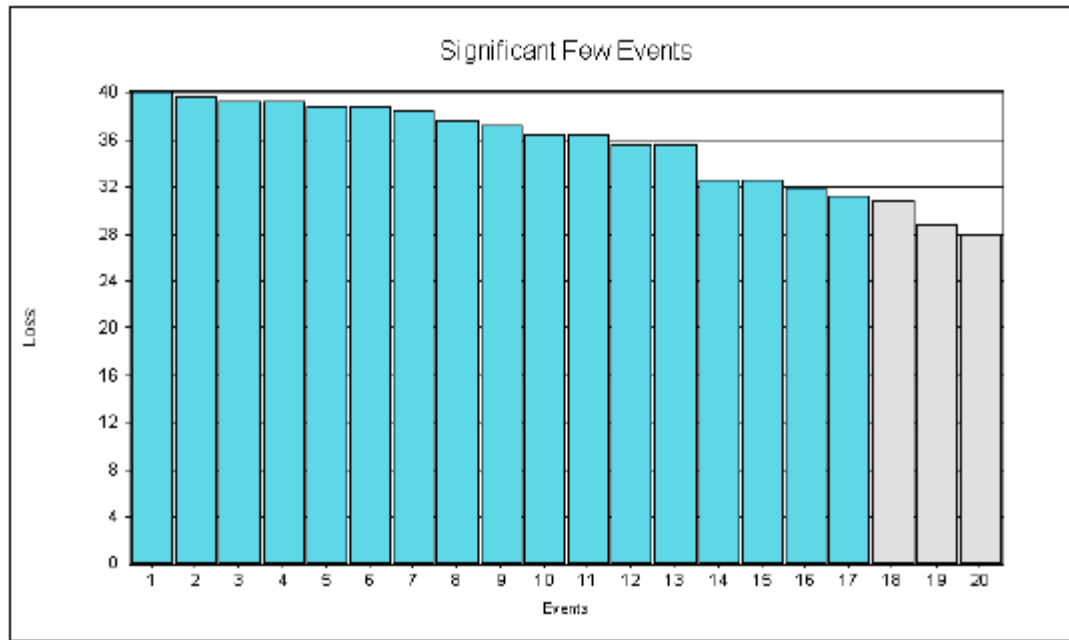
Nephrology	Decision to Use Access Placement Other Than AV fistula	Pt. Ready for Access Placement (?)	3.6	8.5	3.5	8.0	4.0	8.0	3.0	8.5	3.0	8.0	3.4	8.2	27.88
Nephrology	Decision to Use Access Placement Other Than AV fistula	Referral for VA Consult/ Placement	4.0	9.5	4.0	8.5	4.0	9.0	4.0	9.5	4.0	8.0	4.0	8.9	35.60
Surgeon	Decision to Use Access Placement Other Than AV fistula	Patient Education	3.8	9.5	3.5	10	4.0	9.0	3.0	9.0	3.0	9.0	3.5	9.3	32.55
Surgeon	Decision to Use Access Placement Other Than AV fistula	Vessel Mapping	4.0	9.5	4.0	9.0	4.0	10	4.0	10	4.0	10	4.0	9.7	38.80
Surgeon	Decision to Use Access Placement Other Than AV fistula	Appropriate for AV fistula (?)	4.0	9.5	4.0	10	4.0	10	4.0	10	4.0	10	4.0	9.9	39.60
Surgeon	Decision to Use Access Placement Other Than AV fistula	Place AV fistula (YES)	Not Applicable Step for Weighing												
Surgeon	Decision to Use Access Placement Other Than AV fistula	F/U to Monitor Development of AV fistula	4.0	10	4.0	9.0	4.0	10	4.0	10	4.0	10	4.0	9.8	39.20
Surgeon	Decision to Use Access Placement Other Than AV fistula	Are There Problems (?)	Not Applicable Step for Weighing												
Dialysis	Decision to Use Access Placement Other Than AV fistula	Send to Surgeon or IN/RI	4.0	9.0	4.0	9.5	4.0	9.0	4.0	9.0	4.0	9.0	4.0	9.1	36.40

Dialysis	Decision to Use Access Placement Other Than AV fistula	Diagnosis and Repair	4.0	9.1	4.0	9.1	4.0	9.1	4.0	9.1	4.0	9.1	4.0	9.1	36.40
Surgeon	Decision to Use Access Placement Other Than AV fistula	Second Procedure for AV fistula, Revision if Needed	4.0	10	4.0	10	4.0	10	4.0	10	4.0	10	4.0	10	40.00
Surgeon	Decision to Use Access Placement Other Than AV fistula	Placement of Alternative VA if Needed (AV fistula)	Not Applicable Step for Weighing												
Dialysis	Decision to Use Access Placement Other Than AV fistula	Problem Repaired (?)	Not Applicable Step for Weighing												
ED Detection of CKD (III-V)	Decision to Use Access Placement Other Than AV fistula	Admit to Acute Care (?)	4.0	7.0	4.0	8.0	4.0	7.0	4.0	7.0	4.0	10	4.0	7.8	31.20
Acute Care Hospital	Decision to Use Access Placement Other Than AV fistula	Vessel Preservation	4.0	9.5	4.0	9.5	4.0	10	4.0	9.5	4.0	10	4.0	9.8	39.20
Acute Care Hospital	Decision to Use Access Placement Other Than AV fistula	Referral to Nephrologist	4.0	9.5	4.0	9.0	4.0	9.0	4.0	9.0	4.0	10	4.0	9.3	37.20
Acute Care Hospital	Decision to Use Access Placement Other Than AV fistula	Emergent Dialysis (?)	4.0	8.5	4.0	8.5	4.0	8.0	3.0	9.0	4.0	8.0	3.8	8.4	31.92
Acute Care Hospital	Decision to Use Access Placement Other Than	Patient Education	Not Applicable Step for Weighing												

	AV fistula														
Acute Care Hospital	Decision to Use Access Placement Other Than AV fistula	Catheter Placed (?)	Not Applicable Step for Weighting												
Dialysis	Decision to Use Access Placement Other Than AV fistula	Catheter Only	3.5	7.0	3.5	7.0	3.5	7.0	2.0	7.0	3.5	7.0	3.2	7.0	22.40
Dialysis	Decision to Use Access Placement Other Than AV fistula	F/U To Monitor Development of AV fistula	3.5	6.5	2.0	6.0	3.0	5.0	3.0	6.0	3.0	5.0	2.9	5.7	16.53
Dialysis	Decision to Use Access Placement Other Than AV fistula	Cannulate Mature AV fistula or AVG	3.8	9.5	3.5	9.5	3.5	9.0	3.5	9.0	4.0	7.0	3.7	8.8	32.56
Dialysis	Decision to Use Access Placement Other Than AV fistula	Maintain Access Through Surveillance & Monitoring	4.0	9.0	4.0	9.0	4.0	10.0	4.0	10.0	4.0	10.0	4.0	9.6	38.40
Dialysis	Decision to Use Access Placement Other Than AV fistula	Are There Problems (?)	Not Applicable Step for Weighing												

Exhibit 4a

FMEA Significant Few Chart (Refer to page 59 for full list of events)



ID	Event	Mode	RPN
1	Decision to Use Access Placement Other than AVF	Second Proc. for AVF Revision if Needed	40
2	Decision to Use Access Placement Other than AVF	Appropriate for AVF (?)	39.6
3	Decision to Use Access Placement Other than AVF	F/U to Monitor Dev. of AVF	39.2
4	Decision to Use Access Placement	Vessel Preservation	39.2

**Exhibit 5a
FMEA Full Report**

**LEAP™ Analysis SYSTEM ANALYZED:
Vascular Access Placement in
Hemodialysis Patients Basic
FMEA 5/4/2009 Mid-Atlantic
Renal Coalition Rev 3**



**PRINCIPAL ANALYST:
Bob Latino**

RCA Lead Facilitator

Mr. Robert J. Latino

RCA Core Team

Dr. Lawrence Spergel, FACS

Ms. Linda Duvall, BSN, RN

Dr. Jerry Jackson

Dr. Chester Fox

Ms. Valerie Riley, RN, BS

LEAP™ Analysis-Basic FMEA Explanation

The following Basic FMEA was conducted to help us determine the most significant events in our facility that would require a thorough Root Cause Analysis (RCA). This analysis was intended to look at probabilistic events. The analysis delineated which events were most critical to the system in an effort to justify a detailed RCA.

Below is a quick overview of the Basic FMEA process used to determine our facility's Significant Few events:

#	Steps	Description
1.	Define the System to Analyze	Define the scope of the analysis by describing where the process begins and ends.
2.	Define the Team Charter (Terminal Objective)	Define why this team was put together and when will they know they have been successful.
3.	Define Probability and Severity	Define the criteria for selecting a certain value for Probability and Severity.
4.	Define Loss	Define "What is a loss?" in the current business environment in the system chosen to be analyzed.
5.	Draw a Process Flow Diagram	Describe the system chosen to analyze in the form of a block diagram showing the process subsystems.
6.	Fill Out the Basic FMEA Worksheet	Obtain the necessary event data to populate the Basic FMEA worksheet.
7.	Identify the Significant Few	Identify the events that represent the 80% of the losses.
8.	Issue a report	Communicate results.
9.	Conclusion Summary	Summarize conclusions drawn from the analysis.
10.	Recommendations	Delineate the preferred path forward.

Probability Level Severity

Step 1 - Define the System to Analyze

Before beginning the analysis, we defined which system we wished to analyze. This was, in essence, an effort to determine the scope of the analysis; where it began and where it ended.

In this analysis, our System to Analyze was identified as:

Vascular Access Placement in Hemodialysis Patients

Step 2 - Define the RCA Team Charter (Terminal Objective)

We determined the reason the RCA team was formed in a one or two paragraph statement. This served as the focal point for the team to clearly define its purpose and objective.

The RCA team is chartered to conduct an unbiased analysis of the Decision-Making Process in AV fistula Placement in Hemodialysis Patients. The "Significant Few" events will be identified and recommended for further drill-down, Root Cause Analysis (RCA). All findings and recommendations will be submitted to TEP for review to assist them in developing strategies to address the identified root causes.

Step 3 - Define Probability and Severity

Because the Basic FMEA is a probability analysis technique, certain assumptions had to be made with regards to the criteria for their values. Below are the tables that were chosen to reflect the criteria for selecting Probabilities and Severities in this analysis:

#	Steps	Description
1.	Define the System to Analyze	Define the scope of the analysis process begins and ends.
2.	Define the Team Charter (Terminal Objective)	Define why this team was put to they know they have been succe

Step 4 - Define Loss

What is the definition of loss in the system we have chosen to analyze? This will often vary from business to business, department-to-department and economic environment to economic environment. This was a necessary step to focus our efforts and develop a common understanding of what is a loss to us in this system, today.

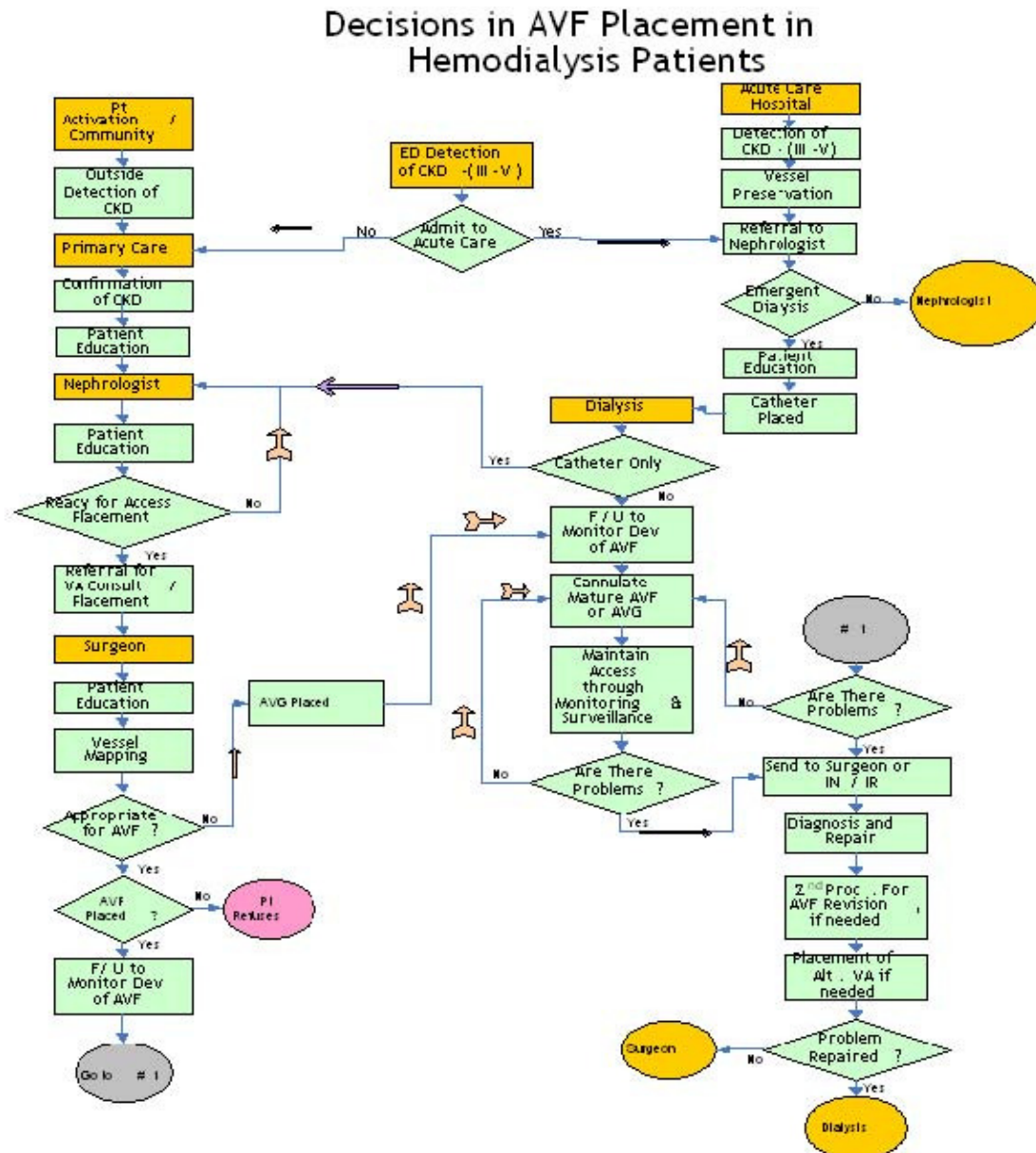
In this analysis, loss was defined as:

Any event or condition affecting the placement of an access other than an AV fistula

Step 5 – Draw a Process Flow Diagram

At this point, we needed to map out the sub-systems of the process we chose to analyze. We used the typical flow charting symbols to develop a simple block diagram to depict the process flow.

In this analysis, our Process Flow Diagram was represented as:



Step 6 – Fill Out the Basic FMEA Worksheet

We now determined where the data would come from to fill out our Basic FMEA worksheet. Several sources were available such as interviews, existing databases, logs, etc. We used the most reliable data source at our disposal.

Once the data was collected and formatted into our worksheet, we did a simple calculation to generate our total loss, for each event in the analysis. The calculation was done automatically in the LEAP™ software. In this analysis, our Basics FMEA Spreadsheet resulted in the following:

(Probability x Severity = Rank Prioritization Number (RPN))

#	Steps	Description
1.	Define the System to Analyze	Define the scope of the analysis by describing where process begins and ends.
2.	Define the Team Charter (Terminal Objective)	Define why this team was put together and when will they know they have been successful.
3.	Define Probability and Severity	Define the criteria for selecting a certain value for Probability and Severity.
4.	Define Loss	Define “What is a loss?” in the current business environment in the system chosen to be analyzed.
5.	Draw a Process Flow Diagram	Describe the system chosen to analyze in the form of block diagram showing the process subsystems.
6.	Fill Out the Basic FMEA Worksheet	Obtain the necessary event data to populate the Basic FMEA worksheet.
7.	Identify the Significant Few	Identify the events that represent the 80% of the losses
8.	Issue a report	Communicate results.
9.	Conclusion Summary	Summarize conclusions drawn from the analysis.
10.	Recommendations	Delineate the preferred path forward.

Probability Level Severity

Level

Frequent	4	Definitive	10
Occasional	3	High	7
Uncommon	2	Moderate	4
Remote	1	Minor	1

Subsystem	Event	Mode	Probability	Severity	RPN
14. Surgeon	Decision to Use Access	Second Proc.	4	10	40

#	Steps	Description
1.	Define the System to Analyze	Define the scope of the analysis by describing where process begins and ends.
2.	Define the Team Charter (Terminal Objective)	Define why this team was put together and when will they know they have been successful.
3.	Define Probability and Severity	Define the criteria for selecting a certain value for Probability and Severity.
4.	Define Loss	Define “What is a loss?” in the current business environment in the system chosen to be analyzed.
5.	Draw a Process Flow Diagram	Describe the system chosen to analyze in the form of block diagram showing the process subsystems.
6.	Fill Out the Basic FMEA Worksheet	Obtain the necessary event data to populate the Basic FMEA worksheet.
7.	Identify the Significant Few	Identify the events that represent the 80% of the losses
8.	Issue a report	Communicate results.
9.	Conclusion Summary	Summarize conclusions drawn from the analysis.
10.	Recommendations	Delineate the preferred path forward.

Probability Level Severity

Level			
Frequent	4	Definitive	10
Occasional	3	High	7
Uncommon	2	Moderate	4
Remote	1	Minor	1

Subsystem	Event	Mode	Probability	Severity	RPN
14. Surgeon	Decision to Use Access Placement Other than AV fistula	Second Proc. for AV fistula Revision if Needed	4	10	40
08. Surgeon	Decision to Use Access Placement Other than AV fistula	Appropriate for AV fistula(?)	4	9.9	39.6
10. Surgeon	Decision to Use Access Placement Other than AV fistula	F/U to Monitor Dev. of AV fistula	4	9.8	39.2
19. Acute	Decision to	Vessel	4	9.8	39.2

#	Steps	Description
1.	Define the System to Analyze	Define the scope of the analysis by describing where process begins and ends.
2.	Define the Team Charter (Terminal Objective)	Define why this team was put together and when will they know they have been successful.
3.	Define Probability and Severity	Define the criteria for selecting a certain value for Probability and Severity.
4.	Define Loss	Define “What is a loss?” in the current business environment in the system chosen to be analyzed.
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7.	Identify the Significant Few	Identify the events that represent the 80% of the losses
8.	Issue a report	Communicate results.
9.	Conclusion Summary	Summarize conclusions drawn from the analysis.
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Probability Level Severity

Level			
Frequent	4	Definitive	10
Occasional	3	High	7
Uncommon	2	Moderate	4
Remote	1	Minor	1

Subsystem	Event	Mode	Probability	Severity	RPN
14. Surgeon	Decision to Use Access Placement Other than AV fistula	Second Proc. for AV fistula Revision if Needed	4	10	40
08. Surgeon	Decision to Use Access Placement Other than AV fistula	Appropriate for AV fistula(?)	4	9.9	39.6
10. Surgeon	Decision to Use Access Placement Other than AV fistula	F/U to Monitor Dev. of AV fistula	4	9.8	39.2
19. Acute	Decision to	Vessel	4	9.8	39.2

#	Steps	Description
1.	Define the System to Analyze	Define the scope of the analysis by describing where process begins and ends.
2.	Define the Team Charter (Terminal Objective)	Define why this team was put together and when will they know they have been successful.
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7.	Identify the Significant Few	Identify the events that represent the 80% of the losses
8.	Issue a report	Communicate results.
9.	Conclusion Summary	Summarize conclusions drawn from the analysis.
10.	Recommendations	Delineate the preferred path forward.

Probability Level Severity

Level

10 4 10 10

Step 7 - Identify the Significant Few

The concept of the Significant Few was derived from a famous Italian Economist named Vilfredo Pareto. Pareto stated that 'In any set or collection of objects, ideas, people and events, a FEW within the sets or collections are MORE SIGNIFICANT than the remaining majority'. Consider these examples:

80% of a bank's assets are representative of 20% or less of its customers

80% of the care given in a hospital is received by 20% or less of its patients

80% of the losses in a manufacturing plant are caused by 20% or less of the events

This means that we only have to perform RCA on 20% or less of our events to reduce or eliminate 80% of our facilities losses.

In order to determine the 'Significant Few', we performed a few simple steps (with the help of the LEAP™ software):

1. Totaled all of the events in the analysis to create a global total loss.
2. Sorted the total loss column in descending order (i.e. highest to lowest)
3. Multiplied the global total loss column by 80% or .80. This gave us the 'Significant Few' loss figure that we will need to determine what the 'Significant Few' events are in our facility.
4. We went to the top of the total loss column and begin adding the top events from top to bottom. When the sum of these losses is equal to or greater than the 'Significant Few' loss figure then those events are your 'Significant Few' events.

In this analysis, our Significant Few events were identified as:

ID	Subsystem	Event	Mode	RPN
1	Surgeon	Decision to Use Access Placement Other than AV fistula	Second Proc. for AV fistula Revision if Needed	40
2	Surgeon	Decision to Use Access Placement Other than AV fistula	Appropriate for AV fistula (?)	39.6
3	Surgeon	Decision to Use Access Placement Other than AV fistula	F/U to Monitor Dev. of AV fistula	39.2
4	Acute Care Hospital	Decision to Use Access Placement Other than AV fistula	Vessel Non-Preservation	39.2
5	Acute Care Hospital	Decision to Use Access Placement Other than AV fistula	Detection of CKD - 3-5	38.8
6	Surgeon	Decision to Use Access Placement Other than AV fistula	Vessel Mapping	38.8
7	Dialysis	Decision to Use Access Placement Other than AV fistula	Maintain Access Through Surv. & Monitoring	38.4
8	Acute Care Hospital	Decision to Use Access Placement Other than AV fistula	Referral to Nephrologist	37.2
9	Surgeon	Decision to Use Access Placement Other than AVF	Send to Surgeon or IN/ IR	36.4
10	Surgeon	Decision to Use Access Placement Other than AVF	Diagnosis and Repair	36.4
11	Nephrology	Decision to Use Access Placement Other than AVF	Patient Education	35.6
12	Nephrology	Decision to Use Access Placement Other than AVF	Referral for VA Consult/Placement	35.6
13	Dialysis	Decision to Use Access Placement Other than AVF	Cannulate Mature AVF or AVG	32.56

14	Surgeon	Decision to Use Access Placement Other than AVF	Patient Education	32.55
15	Acute Care Hospital	Decision to Use Access Placement Other than AVF	Emergent Dialysis (?)	31.92

The total value of the Significant Few losses is 567.94

Step 8 – Issue a report

As with any analysis, it was important to communicate our findings to all interested parties. Our report includes the following items:

- An explanation of the analysis technique.
- The event definition that was utilized.
- The process flow diagram that was utilized.
- The results displayed graphically as well as the supporting spreadsheet lists.
- Recommendations of which events are candidates for Root Cause Analysis.

In summary, Basic FMEA is a fantastic tool for limiting our analysis work to only those things that are of significant importance to the facility. We cannot perform Root Cause Analysis on everything. However, we can use this tool to help narrow our focus to what is 'most' important.

Step 9 – Conclusion Summary

Excluding the eight (8) steps in the process that were not measurable either because they were either not applicable or they were steps without any opportunity to engage patient about placement alternatives, 21 steps were weighed by each of the RCA Team members. The total weight for all weighed steps was 709.92. Sixteen of the weighed 21 steps represented 76.2% (567.94) of the opportunity points in the process to influence patient decisions about placement alternatives.

The top four (4) identified opportunity points were all under the surgeon primary path as follows:

1. Second Procedure for AV fistula Revision if Needed	40.0
2. Decision Point: Was Patient Appropriate for AV fistula	39.6
3. Follow Up to Monitor Development of AV fistula	39.2
4. Vessel Preservation	39.2

Collectively these 4 top opportunities totaled 158 or 22.3% (158/709.92) of the total of all opportunity points.

Step 10 – Recommendations

FMEA Recommendations. It was consensus of the RCA Team that while numerous opportunities were identified, that the overwhelming majority of the Significant Few would be captured by the top four (4). The reasoning for this was based on the belief that many opportunities were subordinate

to these top four (4) and that in the course of the comprehensive RCA, they would be indirectly addressed. Therefore, it was recommended, and carried out that these four (4) top opportunities would be subjected to the scrutiny of the RCA drill down process to better understand the details of the decision-making processes involved.

Exhibit 6a
Root Cause Analysis Verification Log

Root Cause #			Decision to Place other than AV fistula	Sub Category	Source of Verification
1	Education (11)	Patient refusal	Patient education content is not provided in all languages	Patient & Family	Devraj R, Gordon EJ 2009 Quinn RR, Lamping DL, Lok, CE, et al. 2008
2	Education (11)	Patient refusal	Patient is not aware of educational materials that are available	Patient & Family	Hakim RM 2008 Hyland K, Cohen RM, Kwak A, et al 2008 Quinn RR, Lamping DL, Lok, CE, et al. 2008
3	Education (11)	Patient refusal	Educator does not have time to educate patient	System	Hyland K, Cohen RM, Kwak A, et al 2008 Quinn RR, Lamping DL, Lok, CE, et al. 2008
4	Education (11)	Patient refusal	Not seen as cost effective to provide proper supervisory oversight of patient education	System	RCA Expert Opinion
5	Education (11)	Patient refusal	Establishing a patient education training program is not viewed as cost effective	System	RCA Expert Opinion
6	Education (11)	Patient refusal	It's not viewed as cost effective to make an existing patient training program adequate	System	Quinn RR, Lamping DL, Lok, CE, et al. 2008
7	Education (11)	Patient refusal	Educator does not utilize patient education materials that are available	Knowledge Skills Perception	Hyland K, Cohen RM, Kwak A, et al 2008 van Loon M, van der Mark W, Beukers N, et al. 2007
8	Education (11)	Patient refusal	Educator is not culturally competent, cannot relate to patient	Knowledge Skills Perception	RCA Expert Opinion
9	Education (11)	Patient refusal	Reimbursement structure does not support patient education	Reimbursement Policy	RCA Expert Opinion
10	Education (11)	Patient refusal	Patient has inadequate cognitive ability	Patient & Family	Murray AM 2008
11	Education (11)	Patient refusal	Patient has health literacy issue	Patient & Family	Devraj R, Gordon EJ 2009 Lok CE 2007
12	Fears (2)	Patient refusal	Due to lack of patient education, patient is scared of surgery and/or needles	Patient & Family	Figueiredo AE, Viegas A, Monteiro M, et al. 2008 Lacson E, Lazarus JM, Himmelfarb J, et al. 2007 Lok CE 2007 Sands JJ 2007 Yeh SCJ, Huang C, Chou H 2008

Root Cause #			Decision to Place other than AV fistula	Sub Category	Source of Verification
13	Fears (2)	Patient refusal	Patient may suffer from mental illness	Patient & Family	Hakim RM 2008
14	Satisfaction (1)	Patient refusal	Patient is educated on risk of current access (catheter or graft) and is accepting of those risks	Patient & Family	Lok CE 2007 Moist L, Chang SE, Polkinghorne KR, et al 2007
15	Experience (3)	Patient refusal	Patient does not believe that the provider is "pro" AV fistula	Patient & Family	RCA Expert Opinion
16	Experience (3)	Patient refusal	Patient observes poor AV fistula cannulation techniques	Patient & Family	Verhallen AM, Kooistra MP, van Jaarsveld BC 2007
17	Experience (3)	Patient refusal	Patient perceives the AV fistula to be inconvenient compared to other accesses/ won't give up catheter	Patient & Family	Ball L 2005
18	Clinical Contraindication (3)	Physician decision	Physician believes patient has short life expectancy	Clinical Decision	Bessias N, Paraskevas KI, Tziviskou E, et al 2008 Campbell KH, Dale W, Stankus N, et al. 2008 Lazarides MK, Georgiadis GS, Antoniou GA, et al. 2007 Ravani P, Spergel LM, Asif A, et al. 2007 Stolic RV, Trajkovic GZ, Peric VM, et al. 2008 Toussaint ND, Lau KK, Polkinghorne KR, et al. 2007 Vachharajani T, Atray N, Gill S, et al 2008

Root Cause #			Decision to Place other than AV fistula	Sub Category	Source of Verification
19	Clinical Contraindication (3)	Physician decision	Physician believes the patient has inadequate vessels for AV fistula	Clinical Decision	Allon M 2007 Coli L, Donati G, Galaverni MC, et al. 2007 Graham J, Hiremath S, Magner PO, et al. 2008 Koksoy C, Demirci RK, Balci D, et al. 2009 Papanikolaou V, Papagiannis V, Vrochides D, et al 2008 Ravani P, Spergel LM, Asif A, et al. 2007 Suding PN, Wilson SE 2007 Torina PJ, Westheimer EF, Schanzer HR 2008 Vachharajani T, Atray N, Gill S, et al 2008 Wang W, Murphy B, Yilmaz S, et al. 2008 Weyde W, Krajewska M, Letachowics W, et al 2008 Weyde W, Kusztal M, Krajewski, et al 2007 Woo K, Farber A, Doros G, et al 2007
20	Clinical Contraindication (3)	Physician decision	Physician views a vascular access induced ischemia prevents the use of an AV fistula	Clinical Decision	Bachelda P, Utikal P, Kojecky Z, et al 2007 Hammes M, Funaki B, Coe FL 2007 Suding PN, Wilson SE 2007 Tellioglu G, Berber I, Kilicoglu, et al 2008 Walz P, Ladowski JS, Hines A 2007 Weyde W, Kusztal M, Krajewski, et al 2007
21	Surgeon (17)	Physician decision	Surgeon prefers AVG because of less post operative clinical care is required	Knowledge Skills Perception	Hammes M, Funaki B, Coe FL 2007 Huijbregts H, Bots ML, Moll FL, et al. 2007 (2) Keuter XHA, DeSmet AAEA, Kessels AGH, et al. 2008 Lee T, Barker J, Allon M 2007 Pflederer TA, Kwok S, Ketel BL, et al. 2008 Suding PN, Wilson SE 2007 Torina PJ, Westheimer EF, Schanzer HR 2008 Voormolen EHJ, Jahrome AK, Bartels LW, et al. 2009
22	Surgeon (17)	Physician decision	Surgeon believes that reputation is on the line if AV fistula fails	Knowledge Skills Perception	RCA Expert Opinion

Root Cause #			Decision to Place other than AV fistula	Sub Category	Source of Verification
23	Surgeon (17)	Physician decision	Surgeon believes that AV fistulas have a negative impact on their schedules	Knowledge Skills Perception	RCA Expert Opinion
24	Surgeon (17)	Physician decision	Surgeon is irritated by calls from other caregivers about AV fistulas	Knowledge Skills Perception	Polkinghorne KR, Seneviratne M, Kerr PG 2009
25	Surgeon (17)	Physician decision	Surgeon prefers AVG because there are no cannulation issues or problems	Knowledge Skills Perception	Verhallen AM, Kooistra MP, van Jaarsveld BC 2007
26	Surgeon (17)	Physician decision	AV fistula cost more and surgeon is not reimbursed for uninsured patients	Reimbursement Policy	Choi KL, Salman L, Krishnamurthy G, et al 2008 Toussaint ND, Lau KK, Polkinghorne KR, et al. 2007
27	Surgeon (17)	Physician decision	AV fistula takes more surgical time than an AVG but is reimbursed less	Reimbursement Policy	Mannis B, Tonelli M, Yilmaz S, et al. 2005 O'Hare AM, Dudley RA, Hynes DM, et al. 2003 Sands JL, Ferrell LM, Perry MA 2002
28	Surgeon (17)	Physician decision	Surgeon is not paid for post op time and more time is required for AV fistula	Reimbursement Policy	Sands JL, Ferrell LM, Perry MA 2002
29	Surgeon (17)	Physician decision	Reduced payment for simultaneous procedures	Reimbursement Policy	Lacson E, Lazarus JM, Himmelfarb J, et al. 2007

Root Cause #			Decision to Place other than AV fistula	Sub Category	Source of Verification
30	Surgeon (17)	Physician decision	Surgeon does not have AV fistula expertise	Knowledge Skills Perception	Basile C, Lomonte C 2007 Fassiadis N, Morsy M, Siva M, et al. 2007 Gundevia Z, Whalley H, Ferring M, et al. 2008 Huijbregts H, Bots ML, Moll FL, et al. 2007 (1) Huijbregts H, Bots ML, Moll FL, et al. 2007 (2) Lacson E, Lazarus JM, Himmelfarb J, et al. 2007 Levine, MI 2008 Moossavi S, Tuttle AB, Vachharajani TJ, et al. 2008 Pfleiderer TA, Kwok S, Ketel BL, et al. 2008 Ravani P, Spergel LM, Asif A, et al. 2007 Saran R, Elder SJ, Goodkin DA, et al. 2008 Shenoy S 2007 Shrestha PC, Asher J, Shrestha SM, et al. 2007 Thermann F, Ukkat J, Wollert U, et al. 2007 Weale AR, Barwell H, Chant H, et al. 2004
31	Surgeon (17)	Physician decision	Surgeon believes that AV fistula is technically harder to learn than AVG	Knowledge Skills Perception	Choi KL, Salman L, Krishnamurthy G, et al 2008
32	Surgeon (17)	Physician decision	Surgeon does not believe that there is enough AV fistula volume to get comfortable with AV fistula creation	Knowledge Skills Perception	Basile C, Lomonte C 2007 Fassiadis N, Morsy M, Siva M, et al. 2007 Nguyen VD, Griffith CN, Reus J, et al. 2008 Shrestha PC, Asher J, Shrestha SM, et al. 2007 Weale AR, Barwell H, Chant H, et al. 2004
33	Surgeon (17)	Physician decision	There is no surgical competency oversight	Knowledge Skills Perception	Basile C, Lomonte C 2007 Saran R, Elder SJ, Goodkin DA, et al. 2008
34	Surgeon (17)	Physician decision	Surgeon is not competent because AV fistula is technically harder to learn	Knowledge Skills Perception	Basile C, Lomonte C 2007 Keuter XHA, DeSmet AAEEA, Kessels AGH, et al. 2008 Moossavi S, Tuttle AB, Vachharajani TJ, et al. 2008

Root Cause #			Decision to Place other than AV fistula	Sub Category	Source of Verification
35	Surgeon (17)	Physician decision	AV fistula training is not required during residency for general surgery	Knowledge Skills Perception	Basile C, Lomonte C 2007 Saran R, Elder SJ, Goodkin DA, et al. 2008
36	Surgeon (17)	Physician decision	Training fails to have sufficient volume to get comfortable with AV fistula creation	Knowledge Skills Perception	Basile C, Lomonte C 2007 Pflederer TA, Kwok S, Ketel BL, et al. 2008 Saran R, Elder SJ, Goodkin DA, et al. 2008 Weale AR, Barwell H, Chant H, et al. 2004
37	Surgeon (17)	Physician decision	Surgeons receive biased information on AVG, manufacturers expanding indications beyond clinical appropriateness	Knowledge Skills Perception	RCA Expert Opinion
38	Nephrologist (42)	Physician decision	Nephrologist does not want to deal with AV fistula problems	Knowledge Skills Perception	Diskin CJ, Stokes TJ, Dansby L, et al. 2008 Lacson E, Lazarus JM, Himmelfarb J, et al. 2007 Lee T, Barker J, Allon M 2007 Marcus RJ, Marcus DA, Sureshkumar KK, et al 2007 Ravani P, Spergel LM, Asif A, et al. 2007 Toussaint ND, Lau KK, Polkinghorne KR, et al. 2007 Nguyen VD, Lawson L, Ledeen M, et al. 2007 Wasse H, Speckman RA, McClellan WM 2008 Weyde W, Letachowics W, Krajewska M, et al 2008
39	Nephrologist (42)	Physician decision	Nephrologist believes that surgeon does not have experience placing AV fistula	Knowledge Skills Perception	El Minshawy O, El Aziz TA, El Ghani HA 2004
40	Nephrologist (42)	Physician decision	Nephrologist believes that AV fistulas do not mature because of the lack of surgical experience creating AV fistulas	Knowledge Skills Perception	Levine, MI 2008 Nguyen VD, Griffith CN, Reus J, et al. 2008 Shrestha PC, Asher J, Shrestha SM, et al. 2007 Stolic RV, Trajkovic GZ, Peric VM, et al. 2008 Voormolen EHJ, Jahrome AK, Bartels LW, et al. 2009

Root Cause #			Decision to Place other than AV fistula	Sub Category	Source of Verification
41	Nephrologist (42)	Physician decision	Nephrologist believes that AV fistulas do not mature because there is inadequate vessel mapping	Knowledge Skills Perception	Allon M - 2007 Freeman AJ, Gallagher M, Gray-Weale A, et al. - 2008 Ives CL, Akoh JA, George J, et al. 2009 Levine, MI 2008 Moist L, Chang SE, Polkinghorne KR, et al 2007 Pflederer TA, Kwok S, Ketel BL, et al. 2008 Vachharajani T, Atray N, Gill S, et al 2008 Voormolen EHJ, Jahrome AK, Bartels LW, et al. 2009 Wang W, Murphy B, Yilmaz S, et al. 2008
42	Nephrologist (42)	Physician decision	Nephrologist believes that AV fistulas do not mature because inappropriate clinical decisions were made due to inadequate vessel selection	Knowledge Skills Perception	Allon M - 2007 Torina PJ, Westheimer EF, Schanzer HR 2008 Voormolen EHJ, Jahrome AK, Bartels LW, et al. 2009 Wang W, Murphy B, Yilmaz S, et al. 2008
43	Nephrologist (42)	Physician decision	Nephrologist believes that AV fistulas do not mature because there is a failure of monitoring and surveillance	Knowledge Skills Perception	Allon M - 2007 Kiaii M, MacRae JM 2008 Levine, MI 2008 Stolic RV, Trajkovic GZ, Peric VM, et al. 2008 Stracke S, Konner K, Köstlin I, et al. 2007 Suding PN, Wilson SE 2007 Toussaint ND, Lau KK, Polkinghorne KR, et al 2007 Voormolen EHJ, Jahrome AK, Bartels LW, et al. 2009
44	Nephrologist (42)	Physician decision	Nephrologist chooses surgeon based on reasons other than expertise	Political	Choi KL, Salman L, Krishnamurthy G, et al 2008 El Minshawy O, El Aziz TA, El Ghani HA 2004 Wang W, Murphy B, Yilmaz S, et al. 2008

Root Cause #			Decision to Place other than AV fistula	Sub Category	Source of Verification
45	Nephrologist (42)	Physician decision	Nephrologist lack of education on vascular access for sub groups (obese, elderly, etc.)	Knowledge Skills Perception	Bessias N, Paraskevas KI, Tziviskou E, et al 2008 Chemla ES, Morsy M, Anderson L, et al 2007 Chou CY, Tseng YH, Shih CM et al. 2008 Choudhury D, Luna-Salazar C. 2008 Elwakeel HA, Saad EM, Elkiran YM, et al 2007 Ethier J, Mendelssohn DC, Elder SJ, et al. 2008 Field M, McNamara K, Bailey G, et al. 2008 Graham J, Hiremath S, Magner PO, et al. 2008 Kats M, Hawxby AM, Barker J, et al. 2007 Kayacioglu I, Baysal A, Ates M, et al. 2007 Lazarides MK, Georgiadis GS, Antoniou GA, et al. 2007 Lee T, Barker J, Allon M 2007 Lok CE 2007 Marcus RJ, Marcus DA, Sureshkumar KK, et al 2007 Moist L, Chang SE, Polkinghorne KR, et al 2007 Ravani P, Spergel LM, Asif A, et al. 2007 Vachharajani T, Atray N, Gill S, et al 2008 Wang W, Murphy B, Yilmaz S, et al. 2008 Weale AR, Bevis P, Neary WD, et al 2007 Weyde W, Krajewska M, Letachowics W, et al 2008 Yaghoubian A, Lewis RJ, de Virgilio C 2008
46	Nephrologist (42)	Physician decision	Nephrologist receives biased information on AVG and catheters, manufacturers expanding indications beyond clinical appropriateness	Knowledge Skills Perception	RCA Expert Opinion
47	Nephrologist (42)	Physician decision	Nephrologist unwilling to talk to pre-CKD Stage 5 patients about their resistance to AV fistula	CKD 3-4	Nguyen VD, Lawson L, Ledeen M, et al. 2007

Root Cause #			Decision to Place other than AV fistula	Sub Category	Source of Verification
48	Nephrologist (42)	Physician decision	Nephrologist cannot identify when patient will have to start dialysis, creating a delayed decision by the patient	CKD 3-4	Agarwal AK, Patel BM, Haddad NJ 2007 Bhan V, Soroka S, Constantine C, et al 2007 Buck J, Baker R, Cannaby AM, et al 2007 Campbell KH, Dale W, Stankus N, et al. 2008 Curtis BM, Barrett BJ, Djurdjev O, et al. 2007 Lacson E, Lazarus JM, Himmelfarb J, et al. 2007 Wasse H, Speckman R, Frankenfield D, et al 2008
49	Nephrologist (42)	Physician decision	Nephrologist cannot convey the importance for AV fistula to the CKD Stage 5 patient	CKD 3-4	Devraj R, Gordon EJ 2009 Navaneethan SD, Nigewar S, Sengodan M, et al 2007 Nguyen VD, Lawson L, Ledeen M, et al. 2007 Pisoni RL, Arrington CJ, Albert JM, et al. 2009
50	Nephrologist (42)	Physician decision	Nephrologist has to initiate patient on dialysis (urgent) before the patient has made a decision to get an AV fistula	CKD 3-4	Ackoundou-N'Guessan C, Gniosahe A, Guei M, et al. 2008 Agarwal AK, Patel BM, Haddad NJ 2007 Buck J, Baker R, Cannaby AM, et al 2007 Choudhury D, Luna-Salazar C. 2008 Lacson E, Lazarus JM, Himmelfarb J, et al. 2007 Lok CE 2007 Navaneethan SD, Nigewar S, Sengodan M, et al 2007 Sands JJ 2007 Varughese S, John GT, Alexander S, et al. 2007 Wasse H, Speckman R, Frankenfield D, et al 2008 Yoon HE, Chung S, Chung HW, et al. 2009
51	Nephrologist (42)	Physician decision	Nephrologists believes patient has acute renal failure	Knowledge Skills Perception	RCA Expert Opinion
52	Nephrologist (42)	Physician decision	Nephrologist unwilling to talk to prevalent CKD Stage 5 patients about their resistance to AV fistula	Knowledge Skills Perception	Pisoni RL, Arrington CJ, Albert JM, et al. 2009 Rehman R, Schmidt RJ, Moss AH 2009
53	Nephrologist (42)	Physician decision	Patient education content is not provided in all languages	Patient & Family	RCA Expert Opinion

Root Cause #			Decision to Place other than AV fistula	Sub Category	Source of Verification
54	Nephrologist (42)	Physician decision	Nephrologist is not aware of educational materials that are available	Knowledge Skills Perception	Curtis BM, Barrett BJ, Djurdjev O, et al. 2007
55	Nephrologist (42)	Physician decision	Educator is time pressured, covering a large geographic area in many cases	System	RCA Expert Opinion
56	Nephrologist (42)	Physician decision	Not seen as cost effective to provide proper supervisory oversight of staff education	System	Parra E, Ramos R, Betriu A, et al 2008 van Loon M, van der Mark W, Beukers N, et al. 2007
57	Nephrologist (42)	Physician decision	Establishing a staff education training program is not viewed as cost effective	System	Parra E, Ramos R, Betriu A, et al 2008 van Loon M, van der Mark W, Beukers N, et al. 2007
58	Nephrologist (42)	Physician decision	Its not viewed as cost effective to make an existing staff training program adequate	System	Parra E, Ramos R, Betriu A, et al 2008
59	Nephrologist (42)	Physician decision	Reimbursement structure does not support staff education	Reimbursement Policy	Sands JL, Ferrell LM, Perry MA 2002
60	Nephrologist (42)	Physician decision	Educator does not utilize patient education materials that are available	System	Lok CE 2007 Quinn RR, Lamping DL, Lok, CE, et al. 2008
61	Nephrologist (42)	Physician decision	Educator is not culturally competent, cannot relate to patient	Knowledge Skills Perception	RCA Expert Opinion
62	Nephrologist (42)	Physician decision	Patient has inadequate cognitive ability	Patient & Family	Murray AM 2008
63	Nephrologist (42)	Physician decision	Patient has health literacy issue	Patient & Family	Devraj R, Gordon EJ 2009 Wasse H, Speckman R, Frankenfield D, et al 2008
64	Nephrologist (42)	Physician decision	Family influences patient not to get AV fistula because of lack of education	Patient & Family	Devraj R, Gordon EJ 2009
65	Nephrologist (42)	Physician decision	Due to lack of patient education, patient is scared of surgery and/or needles	Patient & Family	Lacson E, Lazarus JM, Himmelfarb J, et al. 2007
66	Nephrologist (42)	Physician decision	Patient fears needles because of comorbid mental illnesses	Patient & Family	Yeh SCJ, Huang C, Chou H 2008

Root Cause #			Decision to Place other than AV fistula	Sub Category	Source of Verification
67	Nephrologist (42)	Physician decision	Patient is educated on risk of current access (catheter or graft) and is accepting of those risks	Patient & Family	Moist L, Chang SE, Polkinghorne KR, et al 2007
68	Nephrologist (42)	Physician decision	Patient does not feel that the provider is "pro" AV fistula	System	Pisoni RL, Arrington CJ, Albert JM, et al. 2009
69	Nephrologist (42)	Physician decision	Patient observes poor AV fistula cannulation techniques	System	RCA Expert Opinion
70	Nephrologist (42)	Physician decision	Patient perceives the AV fistula to be inconvenient compared to other accesses	Patient & Family	Ball L 2005
71	Nephrologist (42)	Physician decision	Patient has proxy who refuses AV fistula	Patient & Family	RCA Expert Opinion
72	Nephrologist (42)	Physician decision	Adequate cannulation training process of staff not viewed as cost effective by organization	System	RCA Expert Opinion
73	Nephrologist (42)	Physician decision	Organizational pressure to reduce labor costs, adequate cannulation training not provided	System	Lacson E, Lazarus JM, Himmelfarb J, et al. 2007
74	Nephrologist (42)	Physician decision	Pressure for fast turnover, faster to turnover catheter patients then AV fistula patients	System	Lacson E, Lazarus JM, Himmelfarb J, et al. 2007
75	Nephrologist (42)	Physician decision	Pressure for fast turnover, faster to turnover catheter patients then AV fistula patients helps reduce labor costs	System	RCA Expert Opinion
76	Nephrologist (42)	Physician decision	Lack of RN education because of organizations focus on short term profits	System	Lacson E, Lazarus JM, Himmelfarb J, et al. 2007
77	Nephrologist (42)	Physician decision	Lack of RN education because of pressure to reduce labor cost	System	RCA Expert Opinion
78	Nephrologist (42)	Physician decision	Lack of tech education because of organizations focus on short term profits	System	Lacson E, Lazarus JM, Himmelfarb J, et al. 2007
79	Nephrologist (42)	Physician decision	Lack of tech education because of pressure to reduce labor costs	System	RCA Expert Opinion

Root Cause #			Decision to Place other than AV fistula	Sub Category	Source of Verification
80	Interventionalists (7)	Physician decision	Interventionalist does not perceive advantage of AV fistula due to failure to properly utilize vessel mapping	Knowledge Skills Perception	Vachharajani T, Atray N, Gill S, et al 2008 Weitzel WF 2008
81	Interventionalists (7)	Physician decision	Interventionalists failure to follow KDOQI because they do not see the advantage of AV fistula	Knowledge Skills Perception	Bradbury BD, Chen F, Furniss A, et al. 2009
82	Interventionalists (7)	Physician decision	Interventionalist does not refer to surgeon as the KDOQI guidelines suggest	Knowledge Skills Perception	Hyland K, Cohen RM, Kwak A, et al 2008 Innes A 2008 Varughese S, John GT, Alexander S, et al. 2007
83	Interventionalists (7)	Physician decision	Interventionalist believes that there is an economic disincentive to refer to surgeons if they were to follow the KDOQI guidelines	Knowledge Skills Perception	RCA Expert Opinion
84	Interventionalists (7)	Physician decision	Interventionalist lacks knowledge on Fistula First guidelines and does not see the advantage of AV fistula	Knowledge Skills Perception	Bradbury BD, Chen F, Furniss A, et al. 2009 Rutkowski M, Mann W, Derosé S, et al. 2009 van Loon M, van der Mark W, Beukers N, et al. 2007 Varughese S, John GT, Alexander S, et al. 2007
85	Interventionalists (7)	Physician decision	Interventionalist does not refer to surgeon as the Fistula First guidelines suggest	Knowledge Skills Perception	Hyland K, Cohen RM, Kwak A, et al 2008 Innes A 2008 Vachharajani T, Atray N, Gill S, et al 2008 Varughese S, John GT, Alexander S, et al. 2007
86	Interventionalists (7)	Physician decision	Interventionalist believes that there is an economic disincentive to refer to surgeons if they were to follow Fistula First guidelines	Knowledge Skills Perception	RCA Expert Opinion
87	Vessel Non-preservation (9)		Failure to educate non-nephrologist on acute care setting on vessel preservation with detection of CKD 3-5	CKD 3-4	Agarwal AK, Patel BM, Haddad NJ 2007 Babos K, Lawless G, McClellan W 2008 Hoggard J, Saad T, Schon D, et al. 2008 van Loon M, van der Mark W, Beukers N, et al. 2007 Varughese S, John GT, Alexander S, et al. 2007

Root Cause #			Decision to Place other than AV fistula	Sub Category	Source of Verification
88	Vessel Non-preservation (9)		Failure to educate non-nephrologist in out patient setting on vessel preservation with detection of CKD 3-5	CKD 3-4	Agarwal AK, Patel BM, Haddad NJ 2007 Babos K, Lawless G, McClellan W 2008 Fox CH, Swanson A, Kahn LS, et al 2008 Fox CH, Voleti V, Khan LS, et al. 2008 Hoggard J, Saad T, Schon D, et al. 2008 Khan S, Amedia CA 2008 Kiaii M, MacRae JM 2008 Lamb EJ 2008 Lok CE 2007 van Loon M, van der Mark W, Beukers N, et al. 2007 Varughese S, John GT, Alexander S, et al. 2007
89	Vessel Non-preservation (9)		The lack of an adequate computer flagging system there is a failure to detect CKD 3-5	CKD 3-4	Anothaisintawee T, Rattanasiri R, Ingsathit A, et al. 2009 Babos K, Lawless G, McClellan W 2008 Basile JN 2007 Campbell KH, Dale W, Stankus N, et al. 2008 Castro AF, Coresh J 2009 Fox CH, Swanson A, Kahn LS, et al 2008 Noble E, Johnson DW, Gray N, et al 2008 Rutkowski M, Mann W, Derosé S, et al. 2009 Yoon HE, Chung S, Chung HW, et al. 2009
90	Vessel Non-preservation (9)		Inadequate use of discharge planning there is a failure to detect CKD 3-5	CKD 3-4	Castro AF, Coresh J 2009 Yoon HE, Chung S, Chung HW, et al. 2009
91	Vessel Non-preservation (9)		Failure to educate patients on vessel preservation	CKD 3-4	Fox CH, Voleti V, Khan LS, et al. 2008 Hoggard J, Saad T, Schon D, et al. 2008 Hyland K, Cohen RM, Kwak A, et al 2008 Nguyen VD, Lawson L, Ledeen M, et al. 2007 van Loon M, van der Mark W, Beukers N, et al. 2007

Root Cause #			Decision to Place other than AV fistula	Sub Category	Source of Verification
92	Vessel Non-preservation (9)		Over utilization of PICC lines	CKD 3-4	Agarwal AK, Patel BM, Haddad NJ 2007 Fox CH, Voleti V, Khan LS, et al. 2008 Hoggard J, Saad T, Schon D, et al. 2008 Hyland K, Cohen RM, Kwak A, et al 2008 Sands JJ 2007
93	Vessel Non-preservation (9)		Failure to educate PCPs on vascular access/vessel preservation	CKD 3-4	Ackoundou-N'Guessan C, Gniosahe A, Guei M, et al. 2008 Babos K, Lawless G, McClellan W 2008 Choudhury D, Luna-Salazar C. 2008 Fox CH, Voleti V, Khan LS, et al. 2008 Hoggard J, Saad T, Schon D, et al. 2008 Lacson E, Lazarus JM, Himmelfarb J, et al. 2007 Suding PN, Wilson SE 2007 van Loon M, van der Mark W, Beukers N, et al. 2007
94	Vessel Non-preservation (9)		Failure to influence on vascular access/vessel preservation	CKD 3-4	Ackoundou-N'Guessan C, Gniosahe A, Guei M, et al. 2008 Coli L, Donati G, Galaverni MC, et al. 2007 Hoggard J, Saad T, Schon D, et al. 2008 Vachharajani T, Atray N, Gill S, et al 2008
95	Vessel Non-preservation (9)		Failure for nephrology to approve all PICC lines with GFR less than 45	CKD 3-4	Hoggard J, Saad T, Schon D, et al. 2008

Root Cause #			Inability to Use Once Placed	Sub Category	Source of Verification
96	Failure to Mature (2)	Failure to properly use procedure for AV fistula not maturing	Fail to use endovascular procedures	Knowledge Skills Perception	Allon M 2007Back MR, Maynard M, Winkler A, et al 2008Berman SS, Mendoza B, Westerband A, et al. 2008Campos R, Riella M 2008Clark TW, Cohen RA, Kwak A, Markmann et al. 2007Mercado C, Salman L, Krishnamurthy G, et al. 2008Nassar GE 2008Rajan DK, Chennepiragada SM, Lok CE, et al. 2007Raynaud A, Novelli L, Bourquelot P, et al. 2009Shenoy S 2007Voormolen EHJ, Jahrome AK, Bartels LW, et al. 2009Walz P, Ladowski JS, Hines A 2007
97	Failure to Mature (2)	Failure to properly use procedure for AV fistula not maturing	Fail to surgically revise when indicated	Knowledge Skills Perception	Allon M 2007 Back MR, Maynard M, Winkler A, et al 2008 Balaz P, Rokosny S, Klein D, et al. 2008 Bronder CM, Cull DL, Kuper SG, et al. 2008 Mercado C, Salman L, Krishnamurthy G, et al. 2008 Nassar GE 2008 Papanikolaou V, Papagiannis V, Vrochides D, et al 2008 Ravani P, Spergel LM, Asif A, et al. 2007 Slayden GC, Spergel L, Jennings WC 2008 Stracke S, Konner K, Köstlin I, et al. 2007 Tellioglu G, Berber I, Kilicoglu, et al 2008 van Hoek F, Scheltinga MRM, Luirink M, et al. 2007 van Loon M, van der Mark W, Beukers N, et al. 2007 Voormolen EHJ, Jahrome AK, Bartels LW, et al. 2009 Walz P, Ladowski JS, Hines A 2007 Zheng Y, Liu C, Guan H, et al. 2007

Root Cause #			Inability to Use Once Placed	Sub Category	Source of Verification
98	Failure to Monitor (5)	Failure to monitor development of AV fistula	Not viewed as cost effective to the organization	System	Lok CE 2007 Polkinghorne KR, Seneviratne M, Kerr PG 2009 Schon D, Blume SW, Niebauer K, et al. 2007 Toussaint ND, Lau KK, Polkinghorne KR, et al. 2007 van Loon M, van der Mark W, Beukers N, et al. 2007
99	Failure to Monitor (5)	Failure to monitor development of AV fistula	Patient lacks transportation to get to surgeon	Patient & Family	RCA Expert Opinion
100	Failure to Monitor (5)	Failure to monitor development of AV fistula	Patient and surgeon scheduling conflicts	System	RCA Expert Opinion
101	Failure to Monitor (5)	Failure to monitor development of AV fistula	No surgical follow up appointment made	System	Polkinghorne KR, Seneviratne M, Kerr PG 2009 Raynaud A, Novelli L, Bourquelot P, et al. 2009
102	Failure to Monitor (5)	Failure to monitor development of AV fistula	Patient refuses to go to surgeon	Patient & Family	RCA Expert Opinion
103	Cannulation (12)	Lack of competency in AV fistula cannulation	Organizational Focus on Short Term Profits - Productivity Mentality	System	Schon D, Blume SW, Niebauer K, et al. 2007
104	Cannulation (12)	Lack of competency in AV fistula cannulation	Organizational Pressure to reduce labor costs	System	RCA Expert Opinion
105	Cannulation (12)	Lack of competency in AV fistula	Educator is time pressured, covering a large geographic area and many facilities	System	RCA Expert Opinion

Root Cause #			Inability to Use Once Placed	Sub Category	Source of Verification
		cannulation			
106	Cannulation (12)	Lack of competency in AV fistula cannulation	Educator is not culturally competent and cannot communicate with patient	Knowledge Skills Perception	RCA Expert Opinion
107	Cannulation (12)	Lack of competency in AV fistula cannulation	No provision for self-cannulation training available	System	Lacson E, Lazarus JM, Himmelfarb J, et al. 2007 Verhallen AM, Kooistra MP, van Jaarsveld BC 2007
108	Cannulation (12)	Lack of competency in AV fistula cannulation	Teaching Skills of Educator lacking due to not being viewed as cost effective	System	RCA Expert Opinion
109	Cannulation (12)	Lack of competency in AV fistula cannulation	Adequate training process of educator viewed by organization as not cost effective	System	RCA Expert Opinion
110	Cannulation (12)	Lack of competency in AV fistula cannulation	Establishing a training program for educators is not viewed as cost effective	System	van Loon M, van der Mark W, Beukers N, et al. 2007
111	Cannulation (12)	Lack of competency in AV fistula cannulation	Scarce human resource available due to current reimbursement structure	Reimbursement Policy	Sands JL, Ferrell LM, Perry MA 2002
112	Cannulation (12)	Lack of competency in AV fistula cannulation	Educator fails to use available resources	Knowledge Skills Perception	RCA Expert Opinion
113	Cannulation (12)	Lack of competency in AV fistula cannulation	Lack of organizational ownership and commitment to cannulation credentialing	System	Lok CE 2007

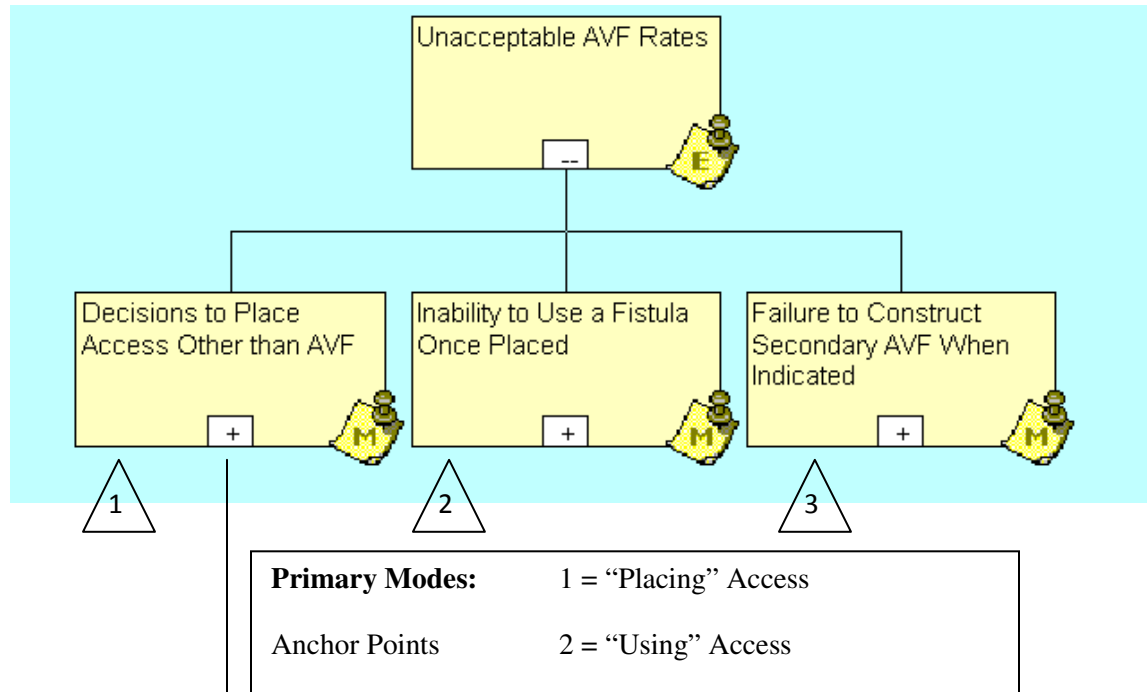
Root Cause #			Inability to Use Once Placed	Sub Category	Source of Verification
114	Cannulation (12)	Lack of competency in AV fistula cannulation	Lack of organizational oversight to cannulation credentialing	System	Lok CE 2007
Root Cause #			Failure to Construct Secondary AV fistula	Sub Category	Source of Verification
115	Patient (5)	Patient refusal	Patient satisfied with graft/catheter and accepting risk	Patient & Family	Lacson E, Lazarus JM, Himmelfarb J, et al. 2007 Quinn RR, Lamping DL, Lok, CE, et al. 2008
116	Patient (5)	Patient refusal	Patients medical comorbid medical conditions interfere with placement	Patient & Family	Marcus RJ, Marcus DA, Sureshkumar KK, et al 2007 Papanikolaou V, Papagiannis V, Vrochides D, et al 2008 Vachharajani T, Atray N, Gill S, et al 2008 Wang W, Murphy B, Yilmaz S, et al. 2008 Wasse H, Speckman RA, McClellan WM 2008
117	Patient (5)	Patient refusal	Family/support systems influences patient to not have AV fistula placed	Patient & Family	RCA Expert Opinion
118	Patient (5)	Patient refusal	Comorbid mental conditions limit patients ability to understand and consent	Patient & Family	RCA Expert Opinion
119	Patient (5)	Patient refusal	Patient lacks cognitive ability to make decision and proxy refuses AV fistula placement	Patient & Family	Murray AM 2008
120	Nephrologist (9)	Nephrologist resistance	Previous bad experience with AV fistula - Mental Barrier	Knowledge Skills Perception	RCA Expert Opinion
121	Nephrologist (9)	Nephrologist resistance	Lack of education related to AV fistula placement	Knowledge Skills Perception	Koksoy C, Demirci RK, Balci D, et al. 2009 Marcus RJ, Marcus DA, Sureshkumar KK, et al 2007

Root Cause #			Failure to Construct Secondary AV fistula	Sub Category	Source of Verification
122	Nephrologist (9)	Nephrologist resistance	Lack of access to surgeon who performs AV fistula placement	System	Huijbregts H, Bots ML, Moll FL, et al. 2007 (2)
123	Nephrologist (9)	Nephrologist resistance	Lack of protocol for secondary AV fistula placement	Knowledge Skills Perception	Ackoundou-N'Guessan C, Gniosahe A, Guei M, et al. 2008 Papanikolaou V, Papagiannis V, Vrochides D, et al 2008 Pflederer TA, Kwok S, Ketel BL, et al. 2008 Slayden GC, Spergel L, Jennings WC 2008 Vachharajani T, Atray N, Gill S, et al 2008
124	Nephrologist (9)	Nephrologist resistance	Surgeon not competent to perform AV fistula placement due to lack of surgical volume	Knowledge Skills Perception	Shrestha PC, Asher J, Shrestha SM, et al. 2007
125	Nephrologist (9)	Nephrologist resistance	Surgeon not competent to perform AV fistula placement due to lack of surgical competency oversight	Knowledge Skills Perception	RCA Expert Opinion
126	Nephrologist (9)	Nephrologist resistance	Education and training limited because of lack of surgical volume	Knowledge Skills Perception	O'Hare AM, Dudley RA, Hynes DM, et al. 2003
127	Nephrologist (9)	Nephrologist resistance	AV fistula education and training not part of General Surgery residency requirements	Knowledge Skills Perception	RCA Expert Opinion
128	Nephrologist (9)	Nephrologist resistance	Lack of surgeon in area to perform AV fistula placement	System	RCA Expert Opinion
129	Interventionalist (3)	Interventionalist resistance	Inability to overcome business self interest	Political	RCA Expert Opinion
130	Interventionalist (3)	Interventionalist resistance	Lack of education and training related to FF	Knowledge Skills Perception	Nikolic B 2008 Vachharajani T, Atray N, Gill S, et al 2008
131	Interventionalist (3)	Interventionalist resistance	Lack of awareness of protocol for AV fistula placement	Knowledge Skills Perception	Koksoy C, Demirci RK, Balci D, et al. 2009 Nikolic B 2008 Vachharajani T, Atray N, Gill S, et al 2008

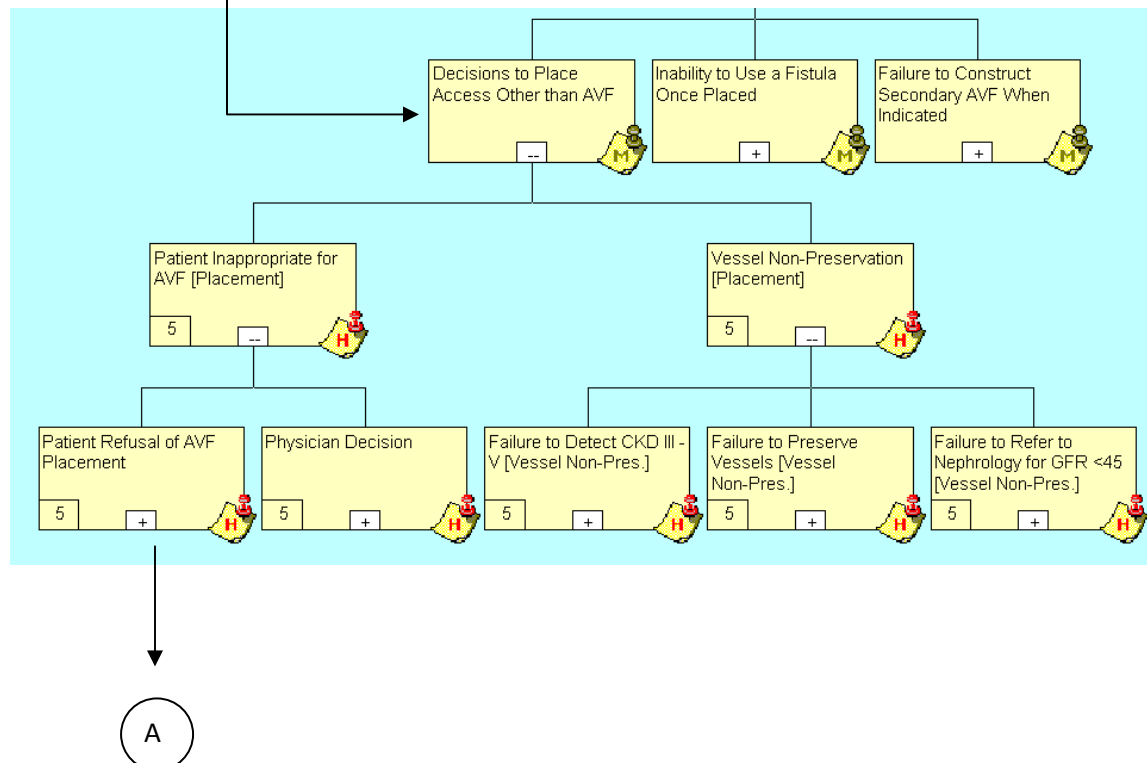
Root Cause #			Failure to Construct Secondary AV fistula	Sub Category	Source of Verification
132	Surgeon (8)	Surgeon resistance	AV fistula education and training not part of General Surgery residency requirements	Knowledge Skills Perception	Basile C, Lomonte C 2007 Collins JP 2008 Collins JP, Gough IR, Civil ID, et al. 2007
133	Surgeon (8)	Surgeon resistance	Surgeon not competent to perform AV fistula placement due to lack of surgical competency oversight	Knowledge Skills Perception	Basile C, Lomonte C 2007 Collins JP 2008 Collins JP, Gough IR, Civil ID, et al. 2007 van Hoek F, Scheltinga MRM, Luirink M, et al. 2007
134	Surgeon (8)	Surgeon resistance	Surgeon not competent to perform AV fistula placement due to lack of surgical volume	Knowledge Skills Perception	Basile C, Lomonte C 2007 Cronenwett JL, Liapis CD 2007 Nguyen VD, Griffith CN, Reus J, et al. 2008 Ravani P, Spergel LM, Asif A, et al. 2007 Shrestha PC, Asher J, Shrestha SM, et al. 2007 Weale AR, Barwell H, Chant H, et al. 2004
135	Surgeon (8)	Surgeon resistance	Education and training limited because of lack of surgical volume	Knowledge Skills Perception	Basile C, Lomonte C 2007 Weale AR, Barwell H, Chant H, et al. 2004
136	Surgeon (8)	Surgeon resistance	Lack of awareness of protocol for AV fistula placement	Knowledge Skills Perception	Clark TW, Cohen RA, Kwak A, Markmann et al. 2007 Koksoy C, Demirci RK, Balci D, et al. 2009 Polkinghorne KR, Seneviratne M, Kerr PG 2009 van Hoek F, Scheltinga MRM, Luirink M, et al. 2007
137	Surgeon (8)	Surgeon resistance	Unwilling to apply protocol related to perceived risk of losing functioning graft	Knowledge Skills Perception	Chou CY, Tseng YH, Shih CM et al. 2008 Tellioglu G, Berber I, Kilicoglu, et al 2008
138	Surgeon (8)	Surgeon resistance	Surgeon unavailable in area to place AV fistula	System	RCA Expert Opinion
139	Surgeon (8)	Surgeon resistance	Unwilling to apply protocol related to complacency and procrastination	Knowledge Skills Perception	Vachharajani T, Atray N, Gill S, et al 2008

Exhibit 7a Root Cause Analysis Logic Tree Breakdown

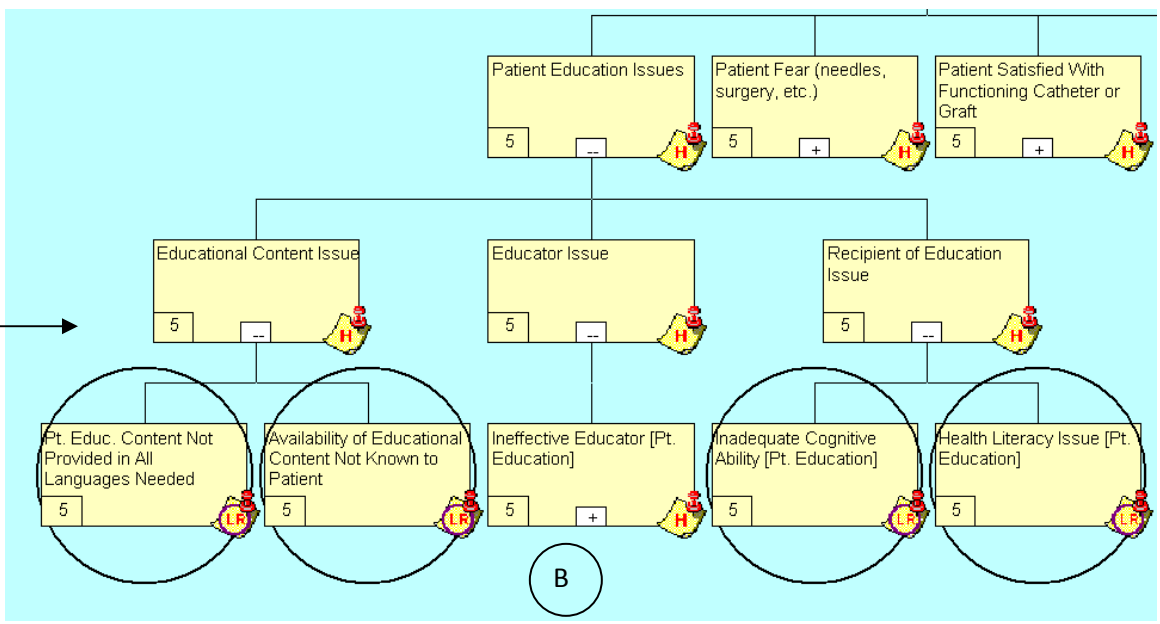
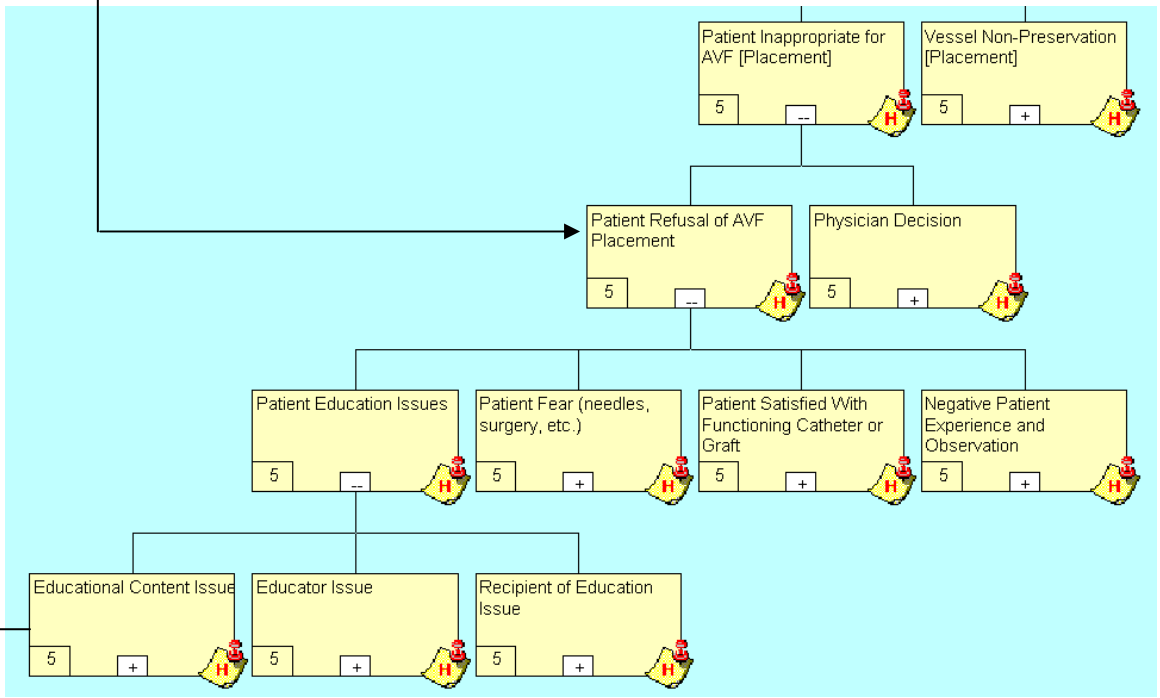
The PROACT[®] Logic Tree Top Box (Event plus Modes)

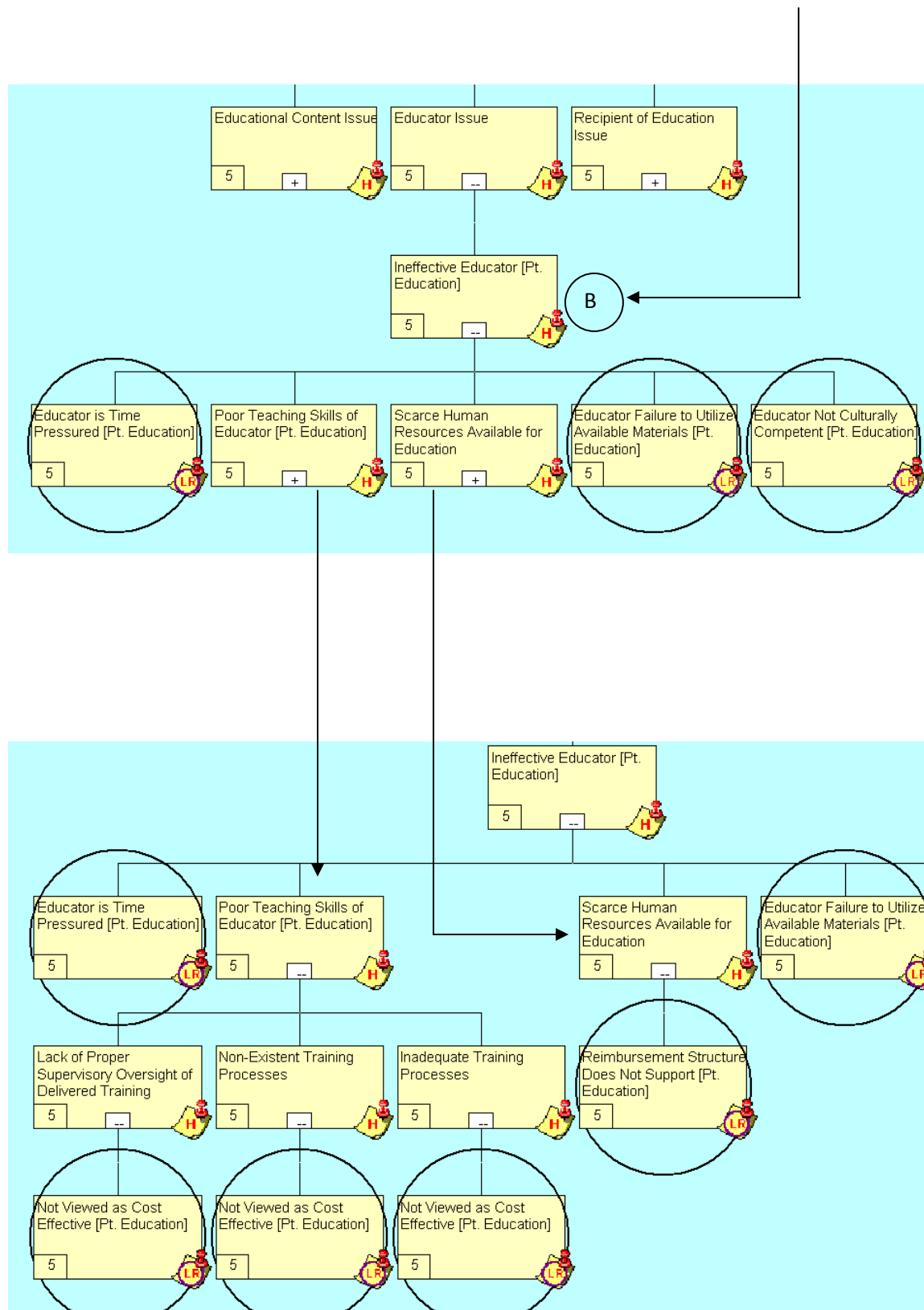


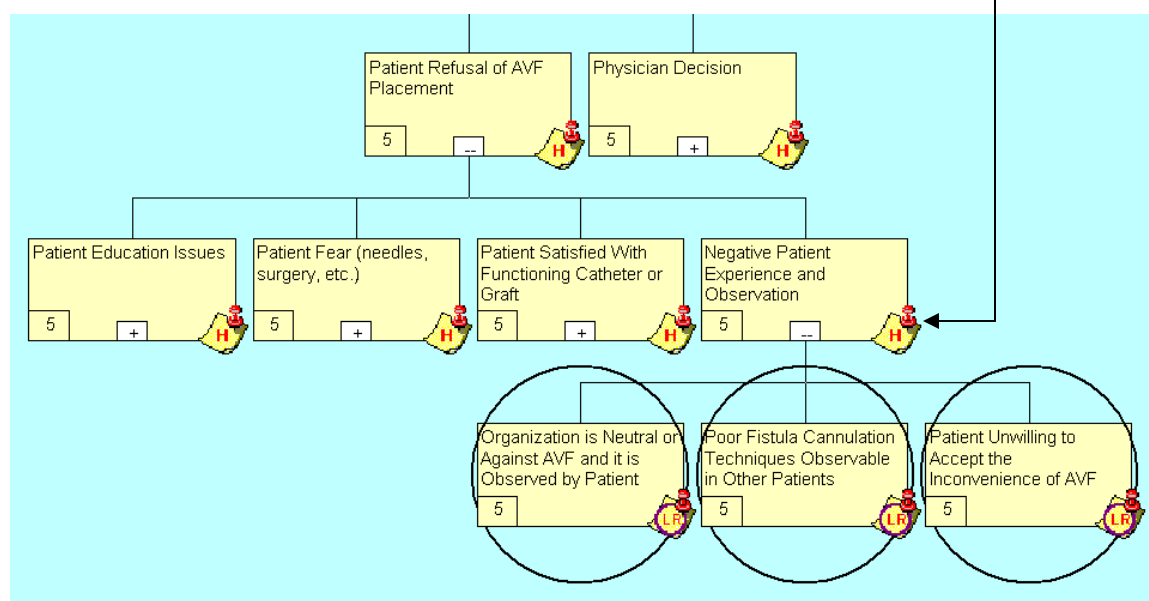
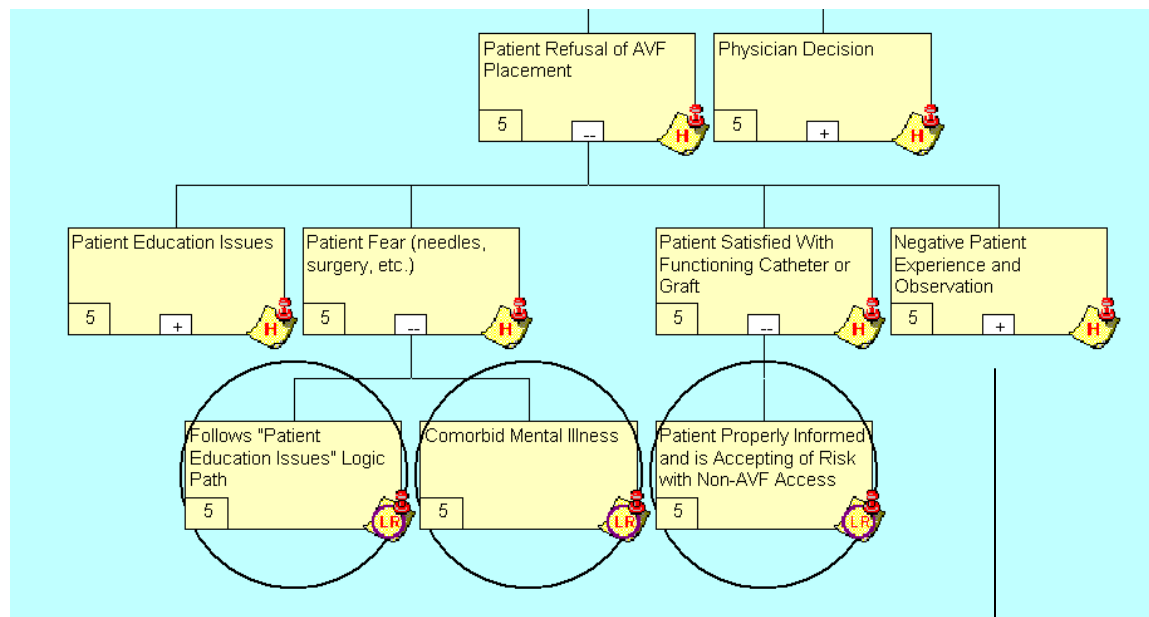
Note: Continue drilling down each level by asking "How could the previous node have occurred?"

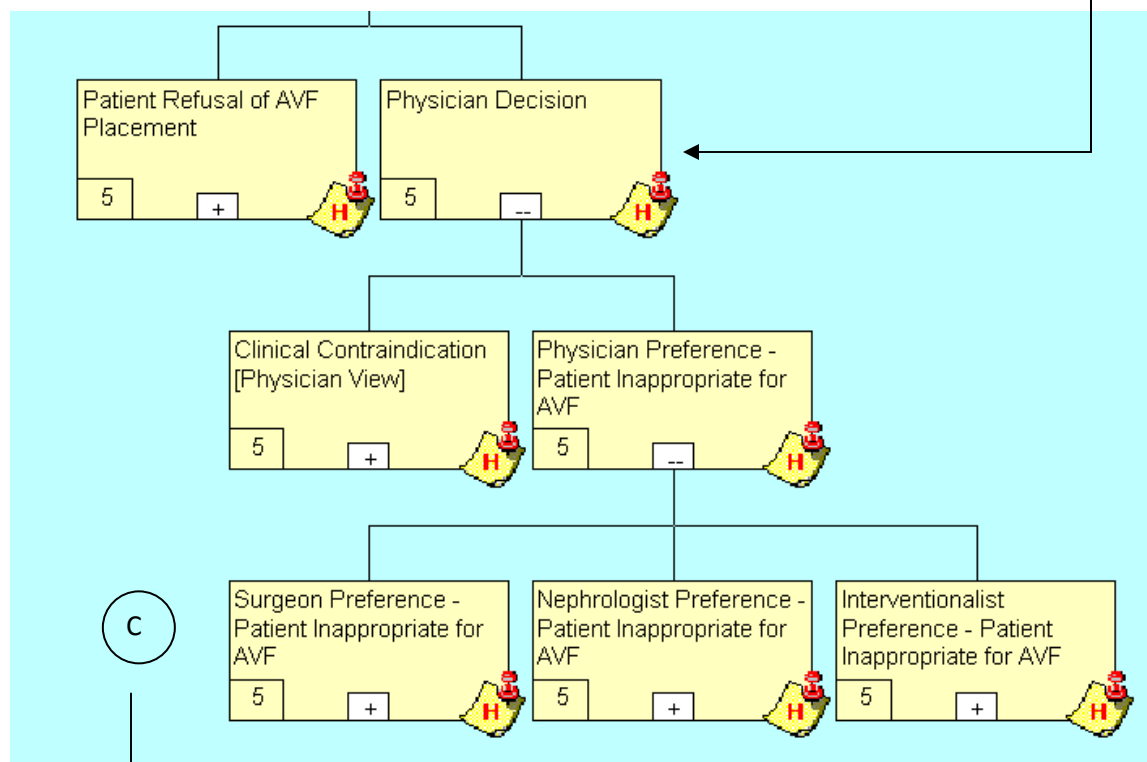
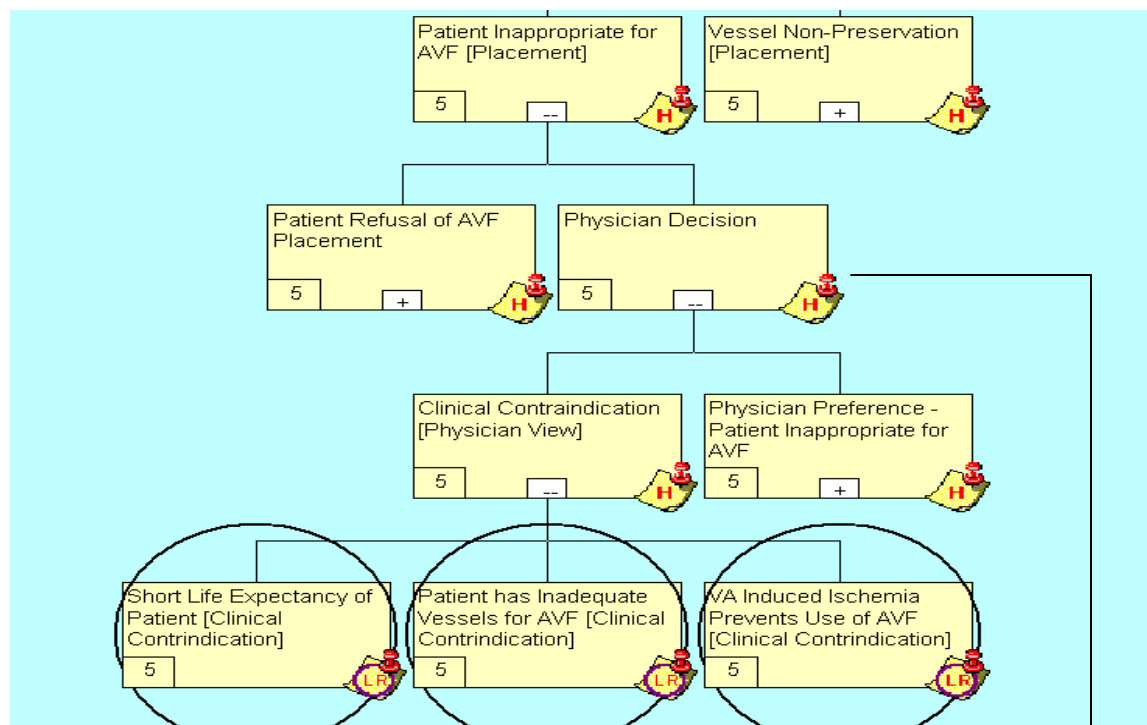


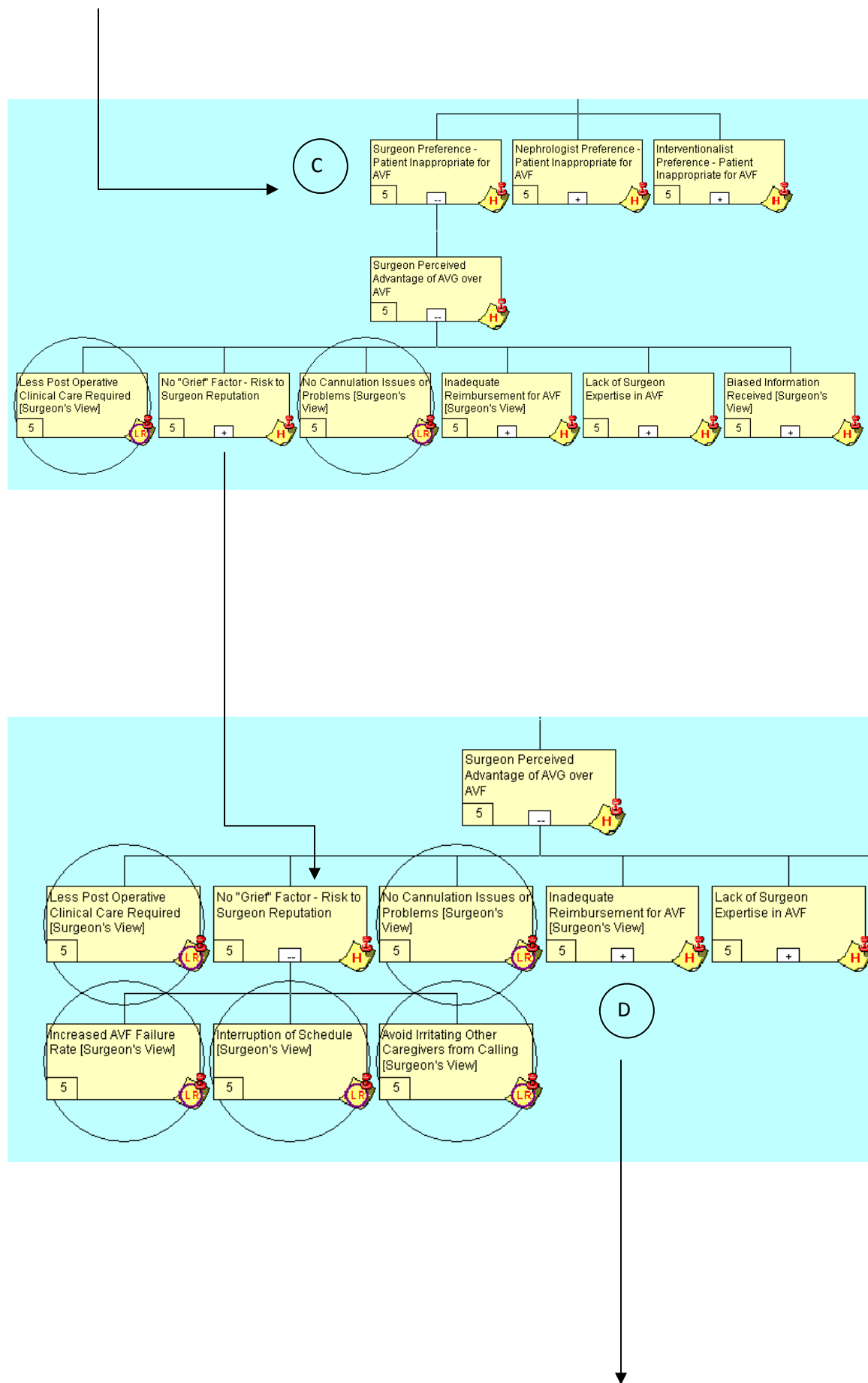
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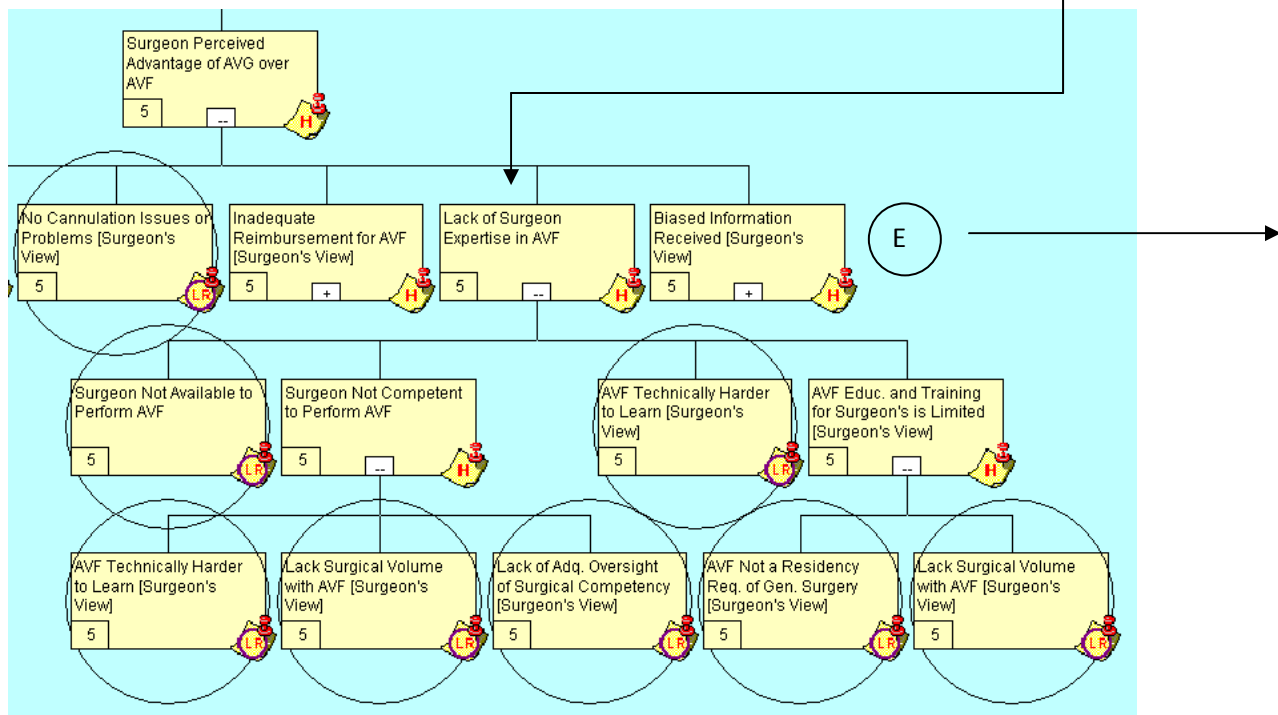
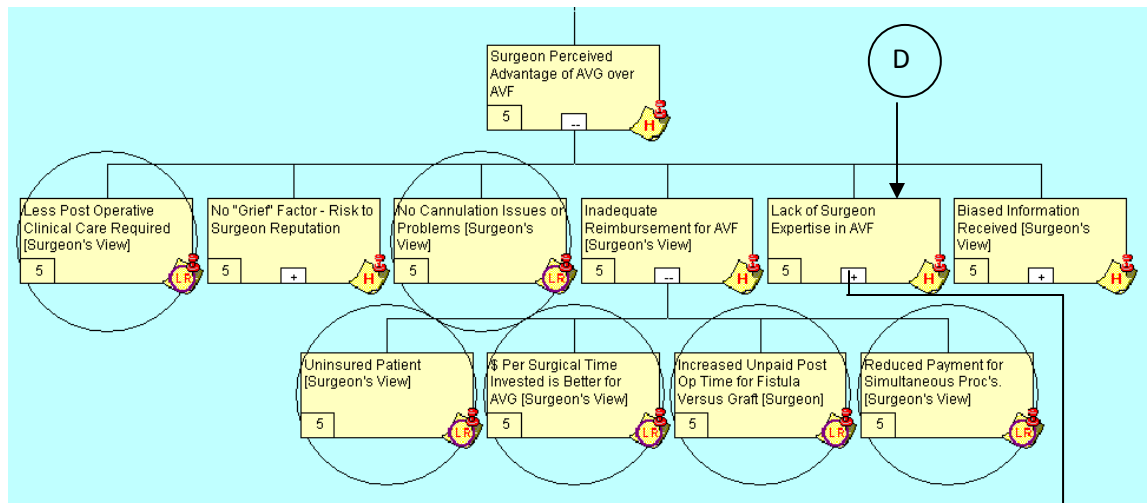


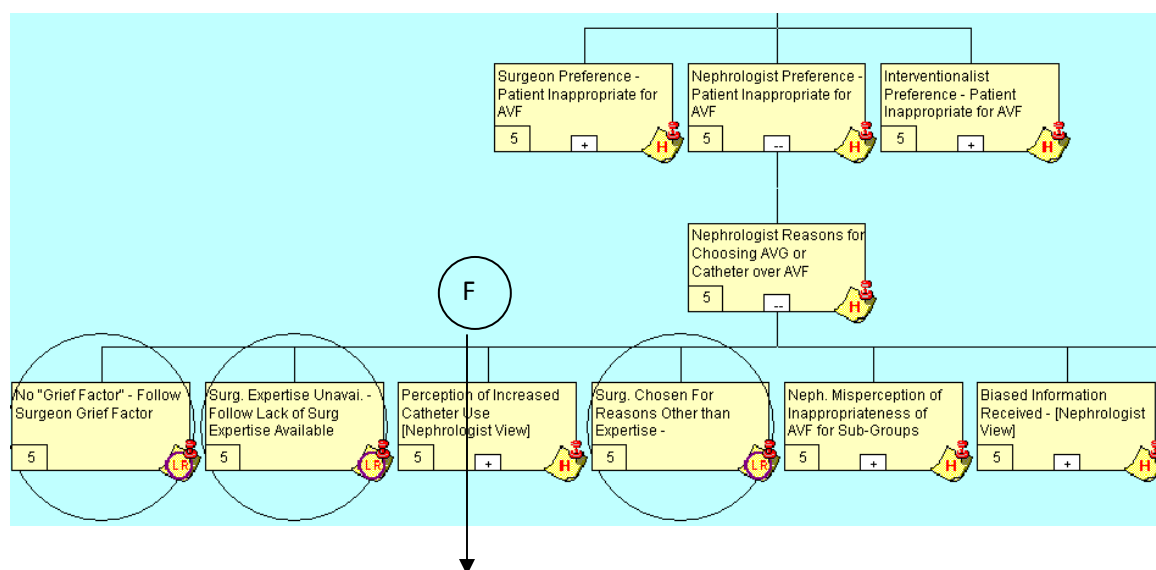
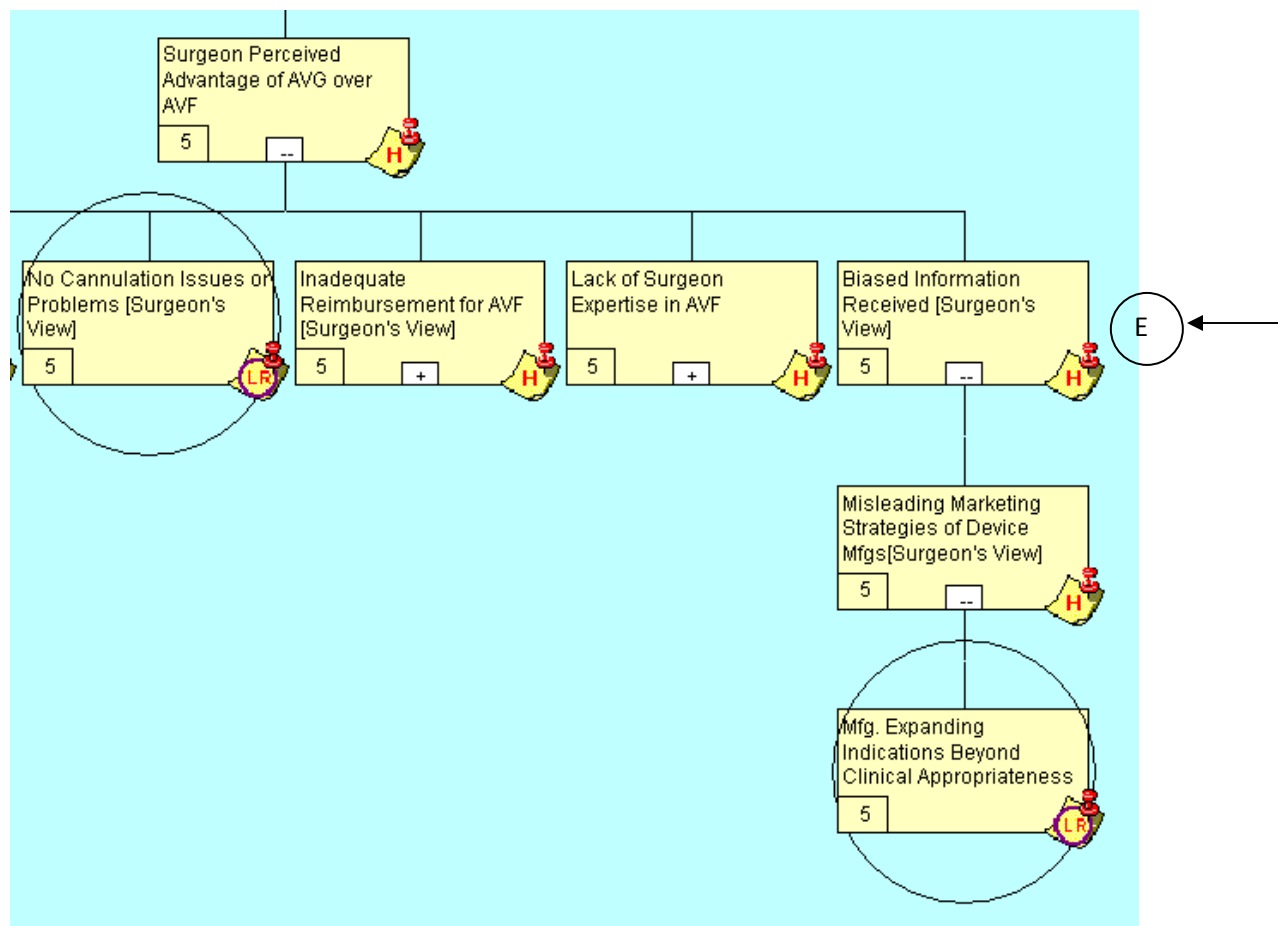


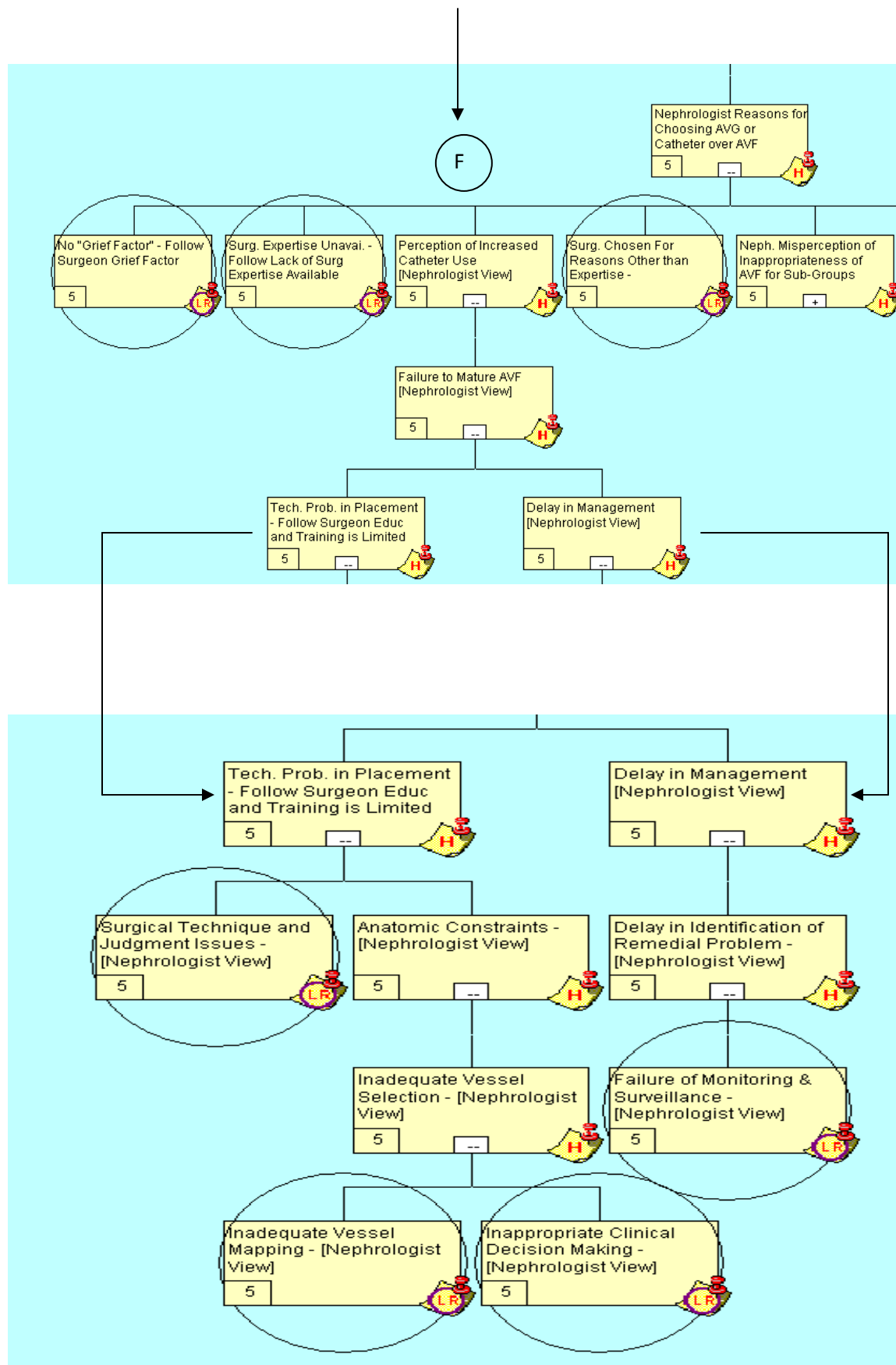


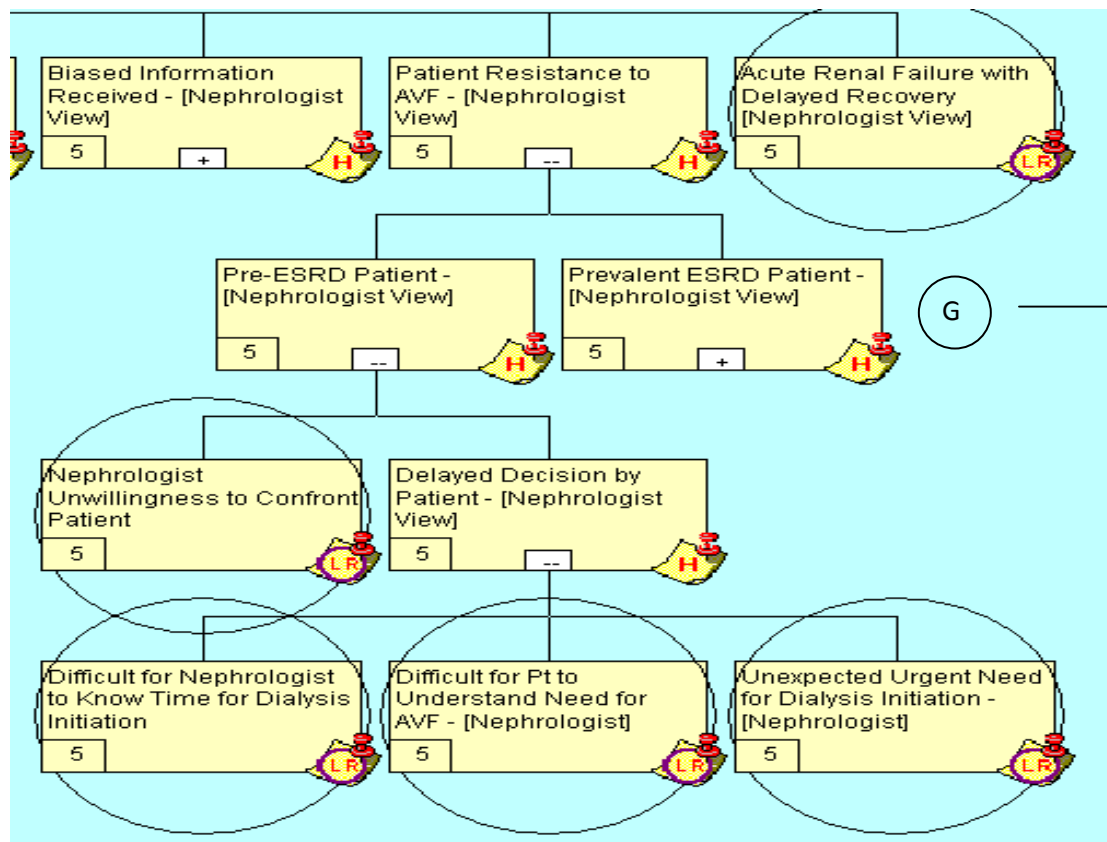
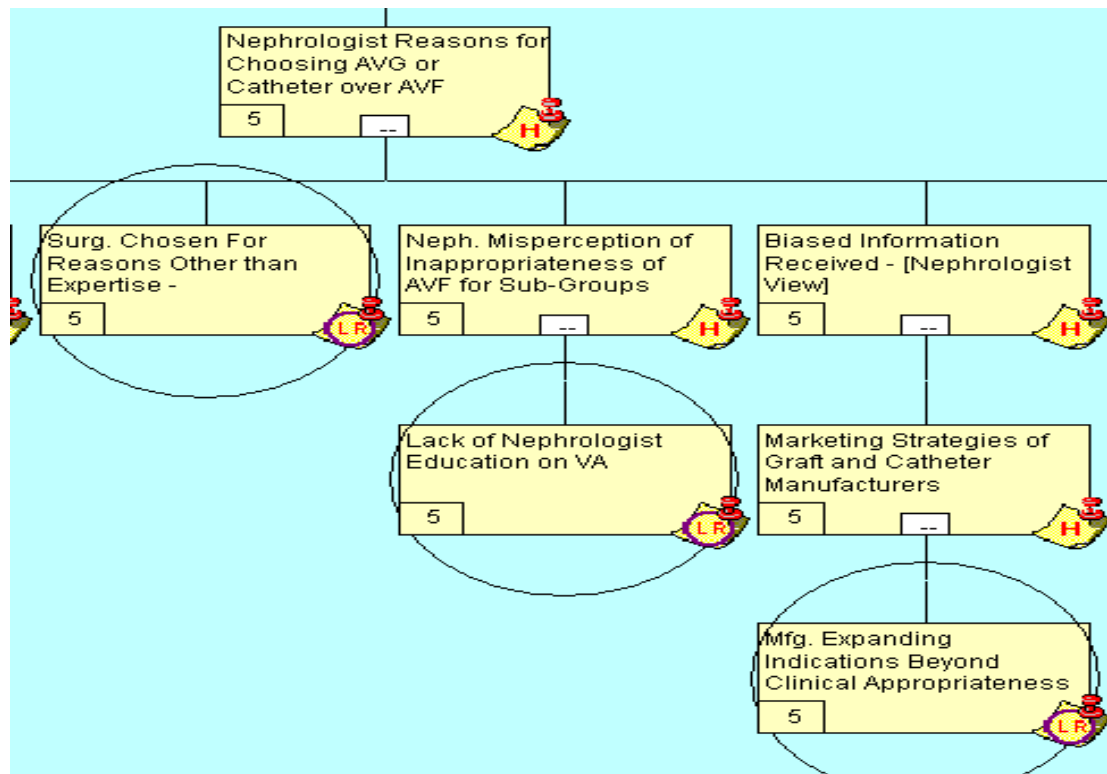


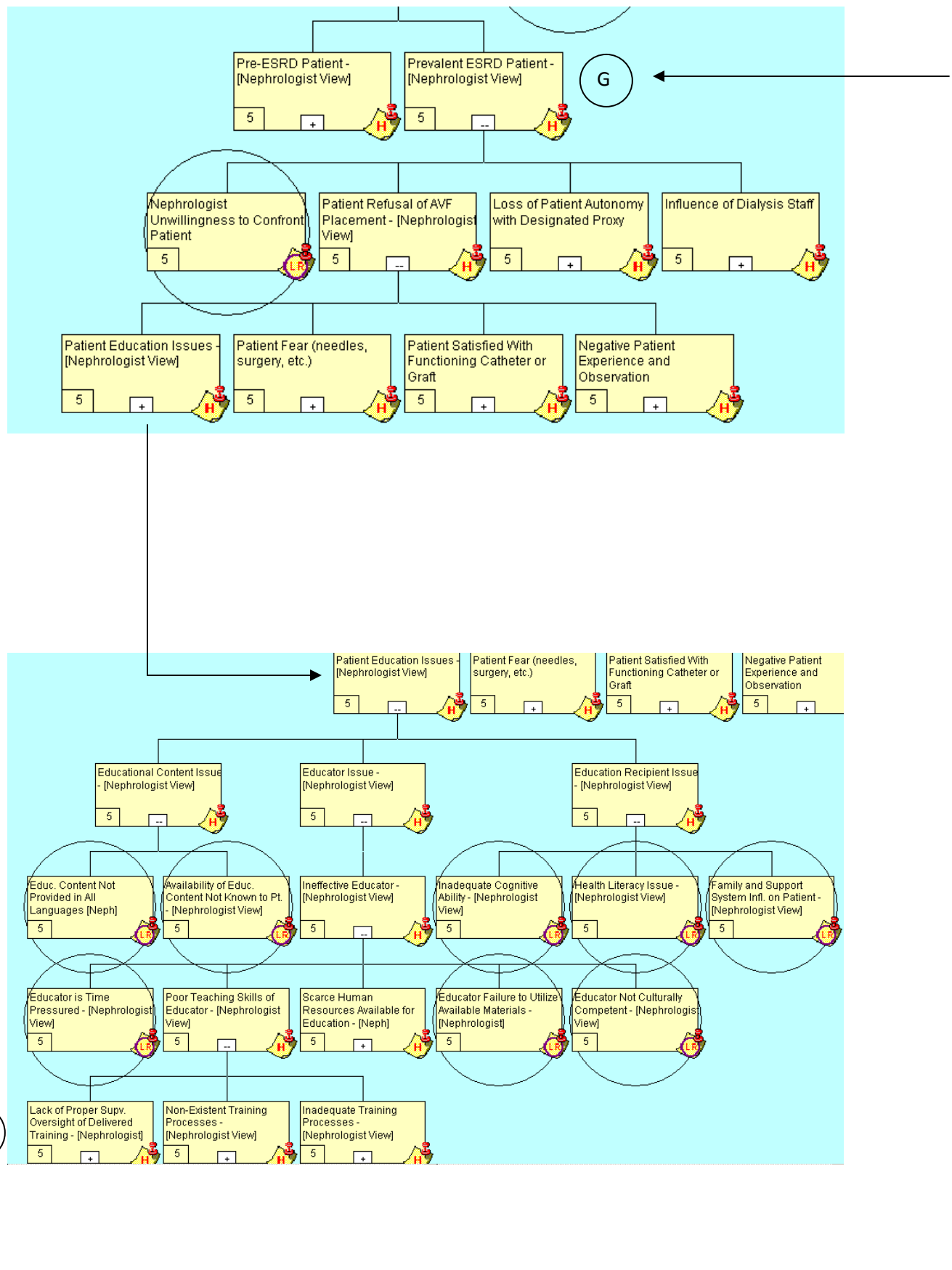


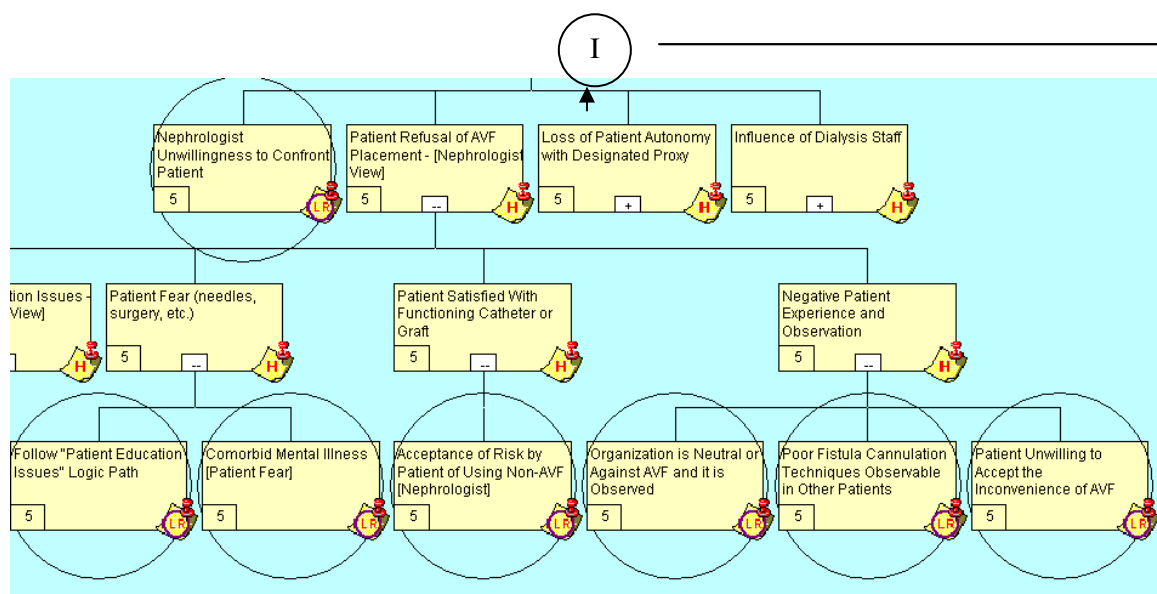
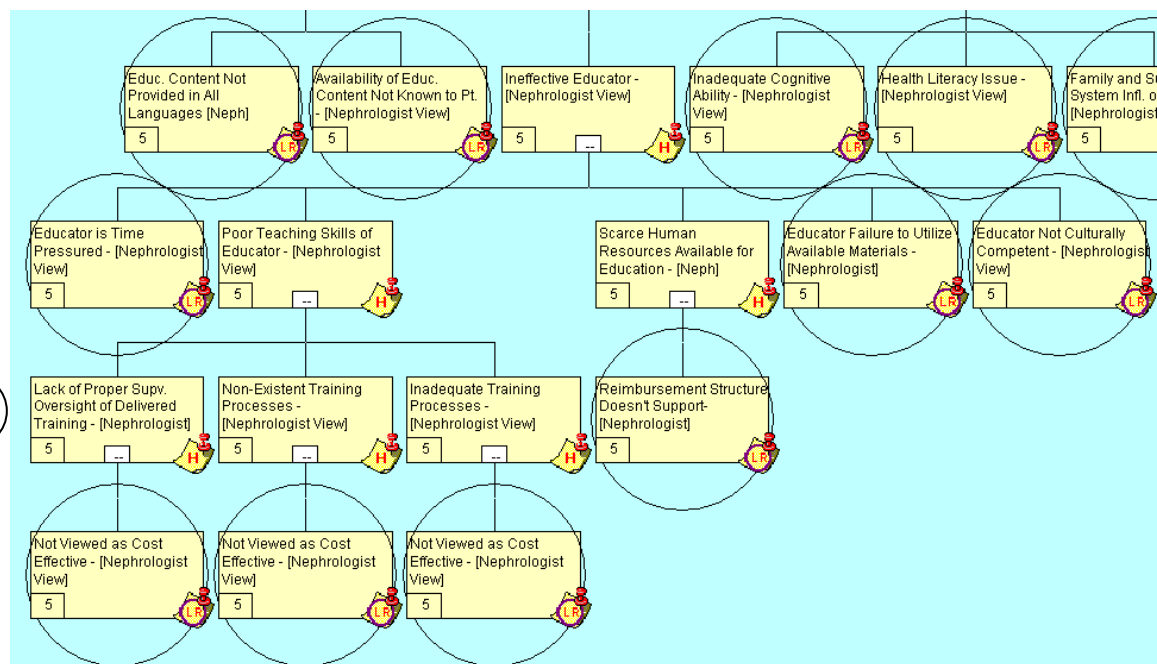


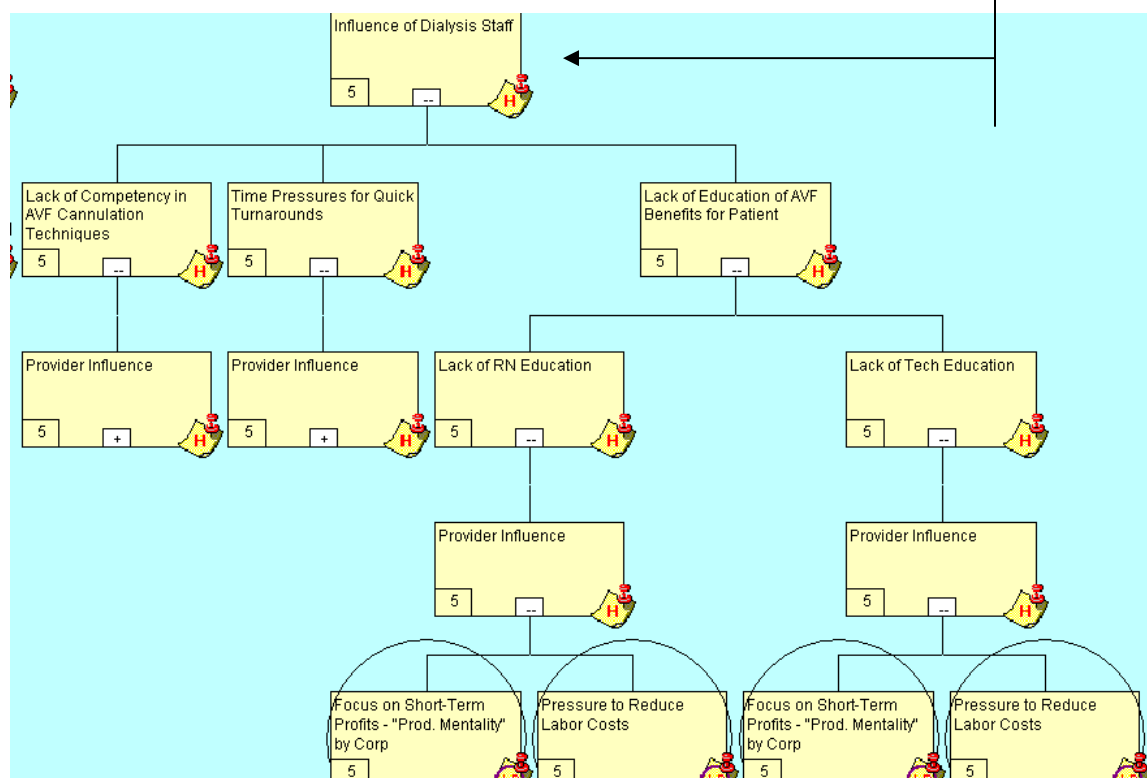
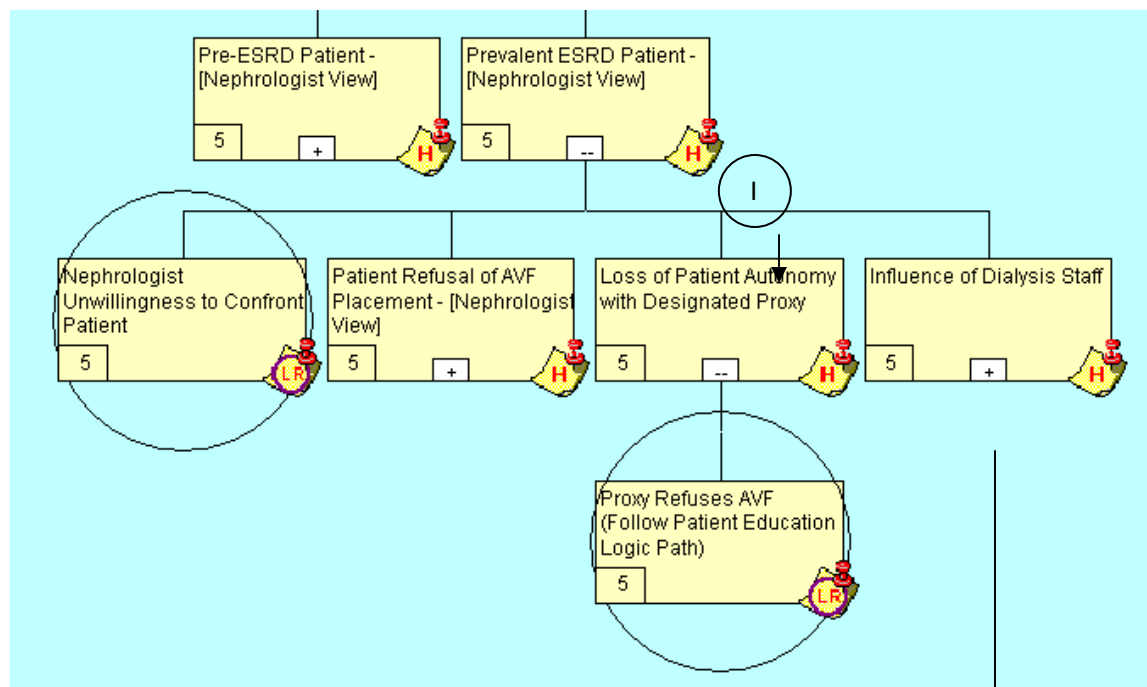




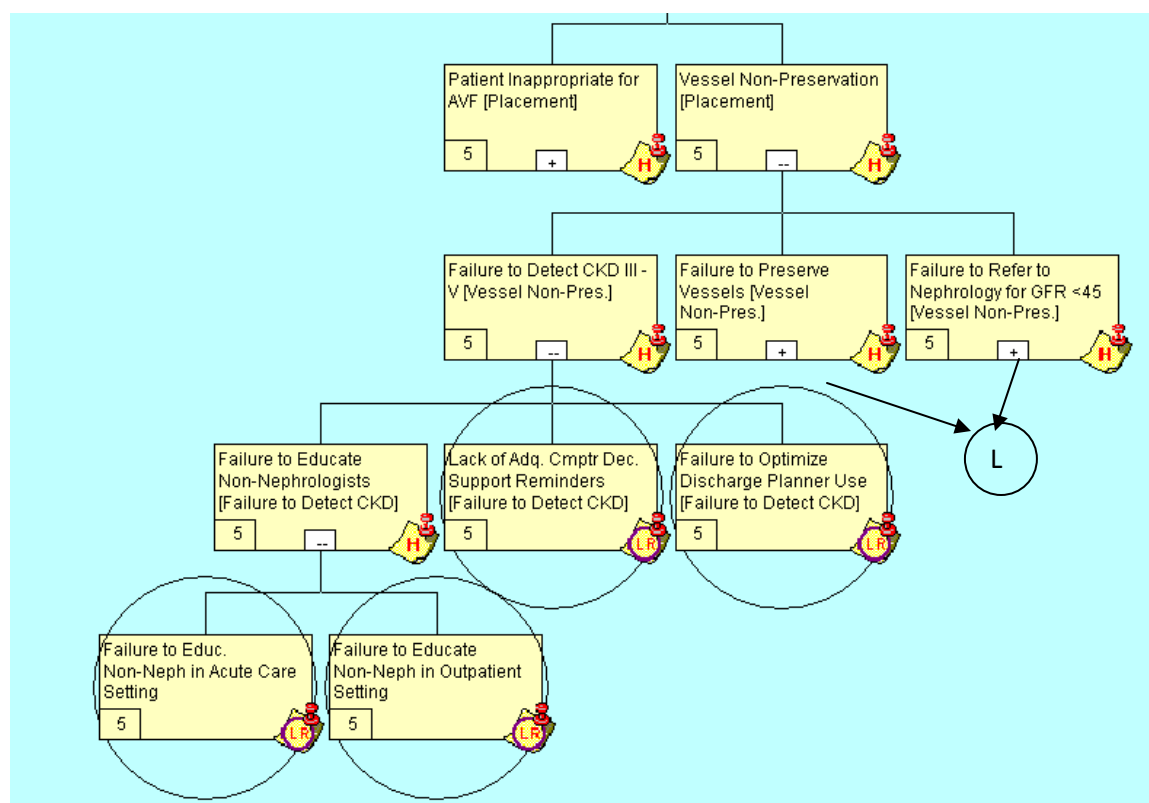
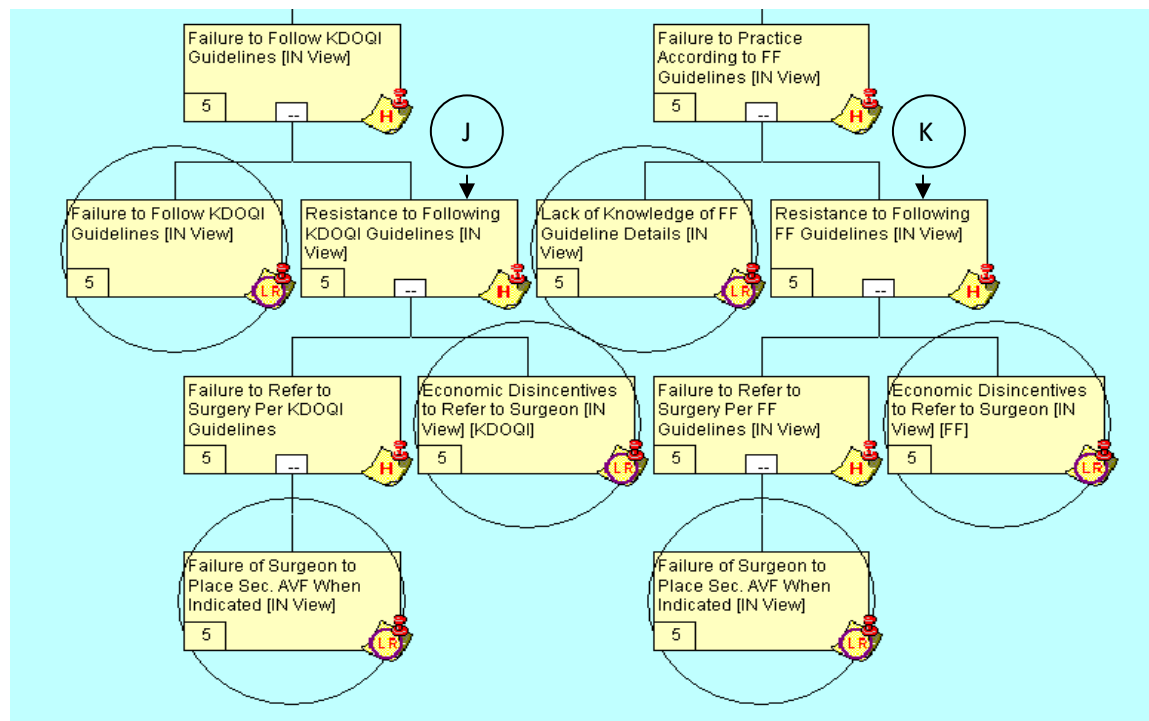


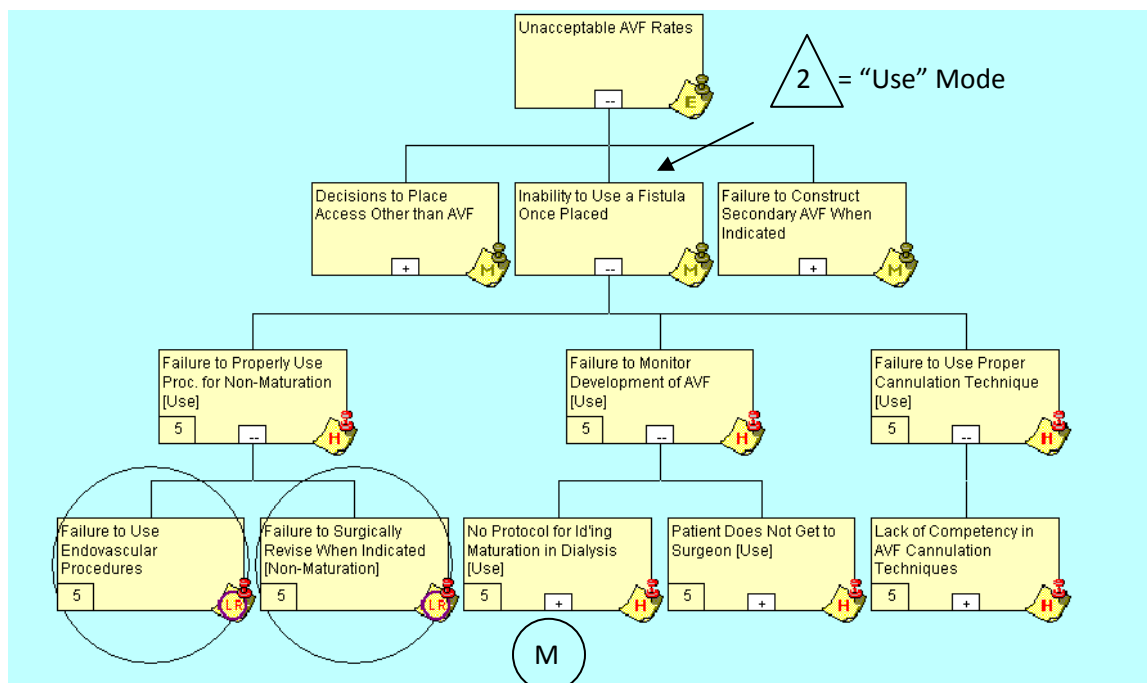
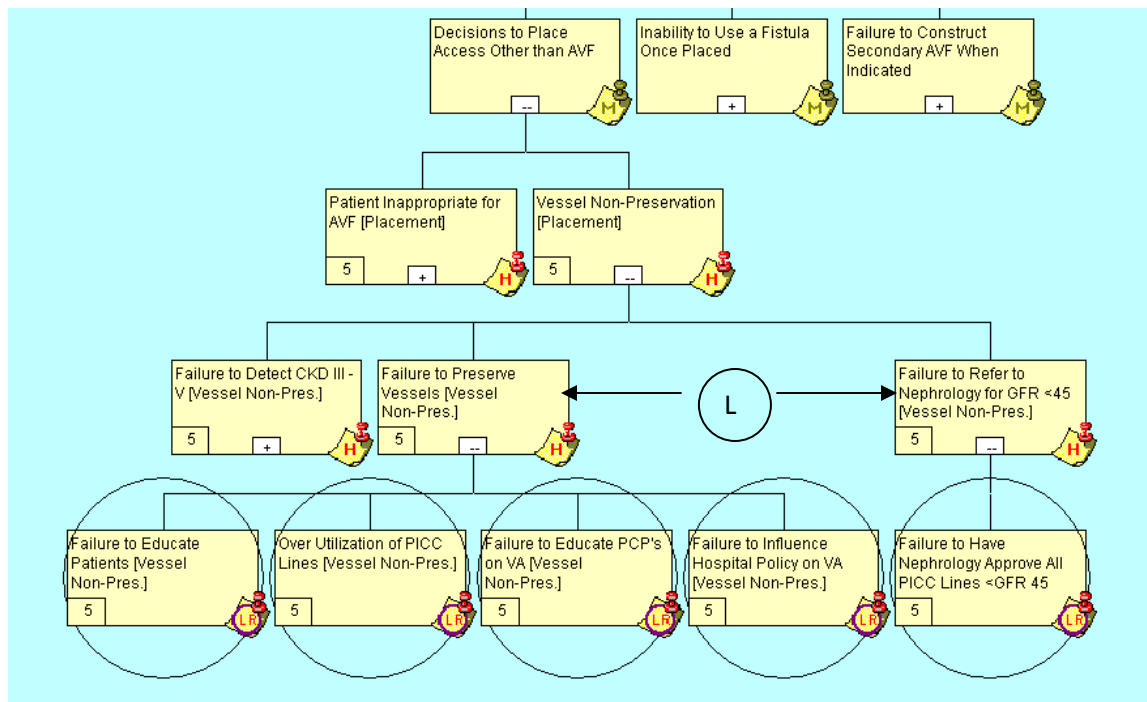


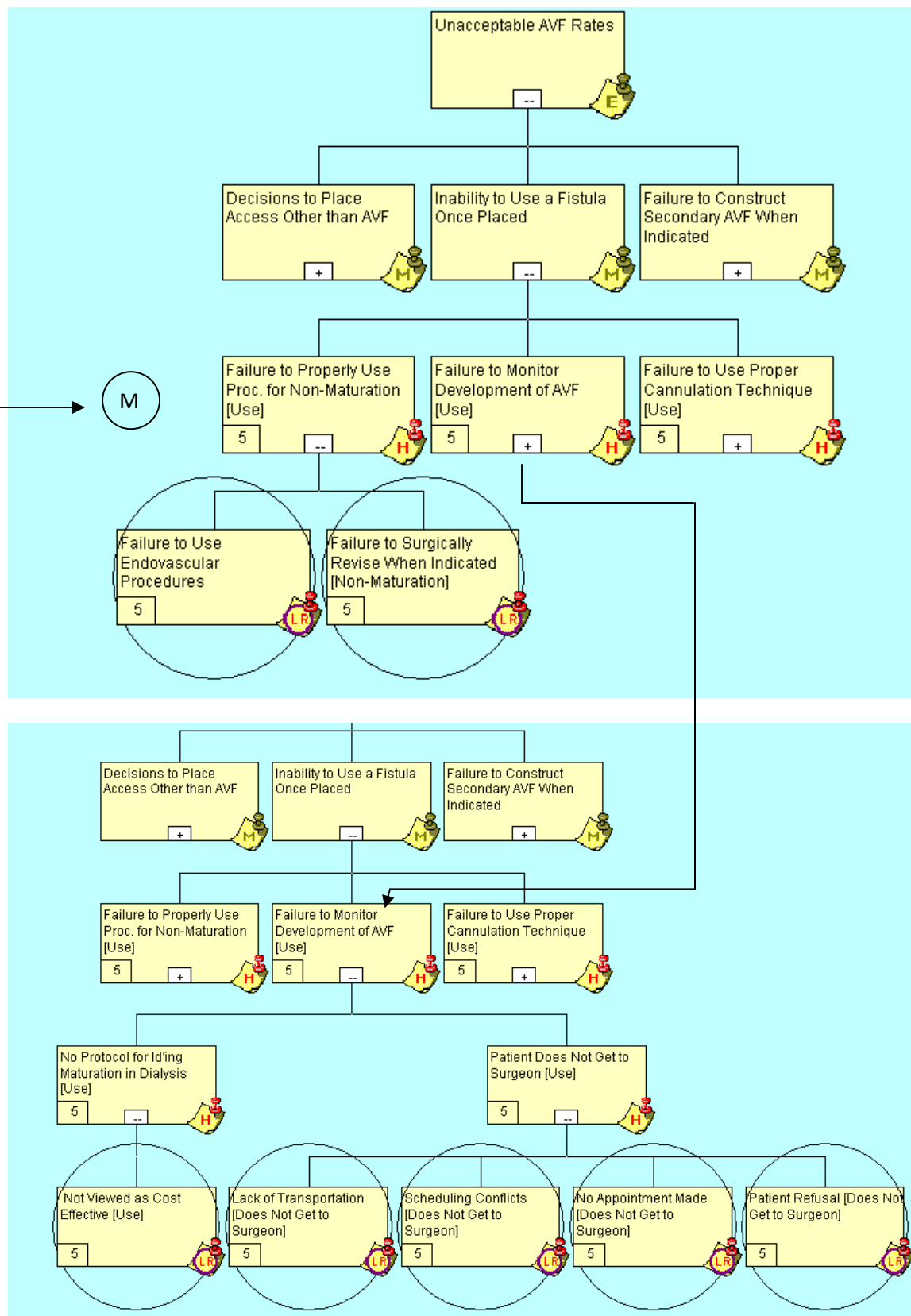


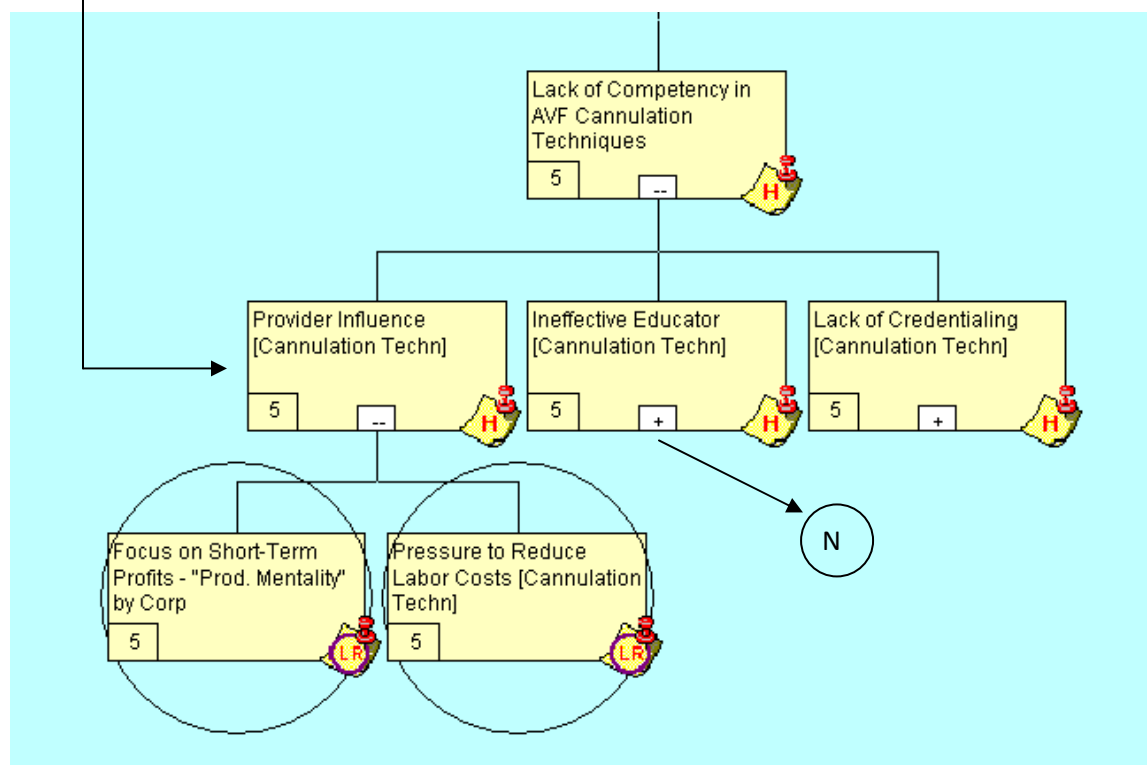
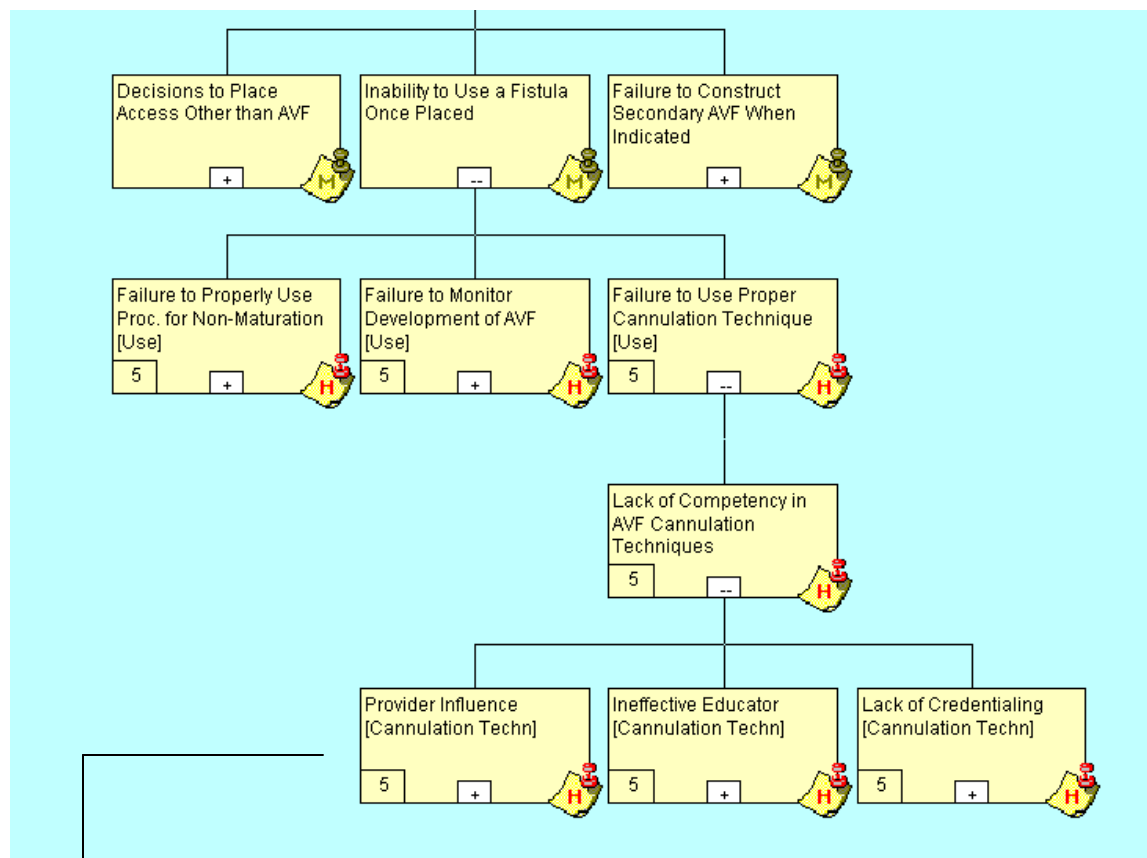


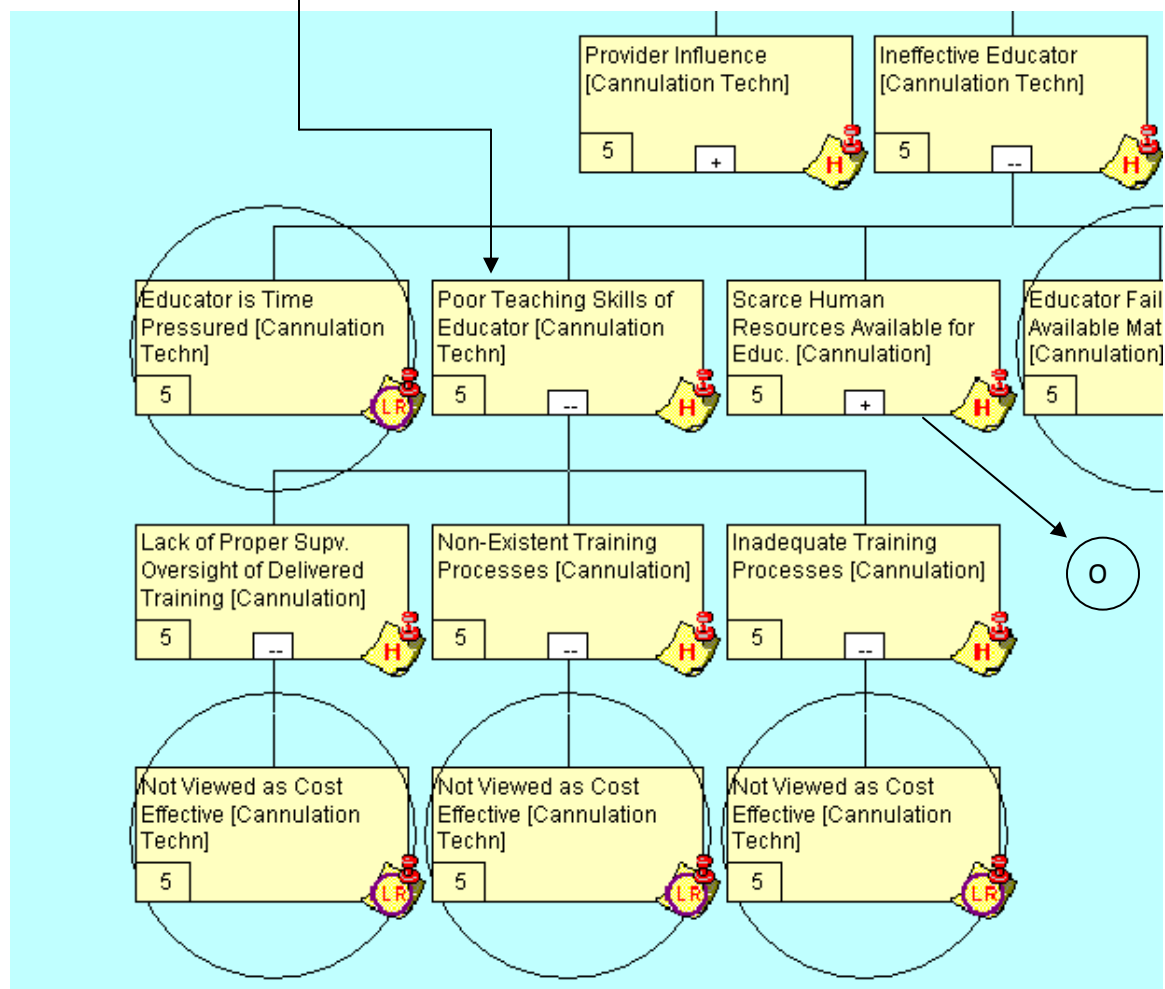
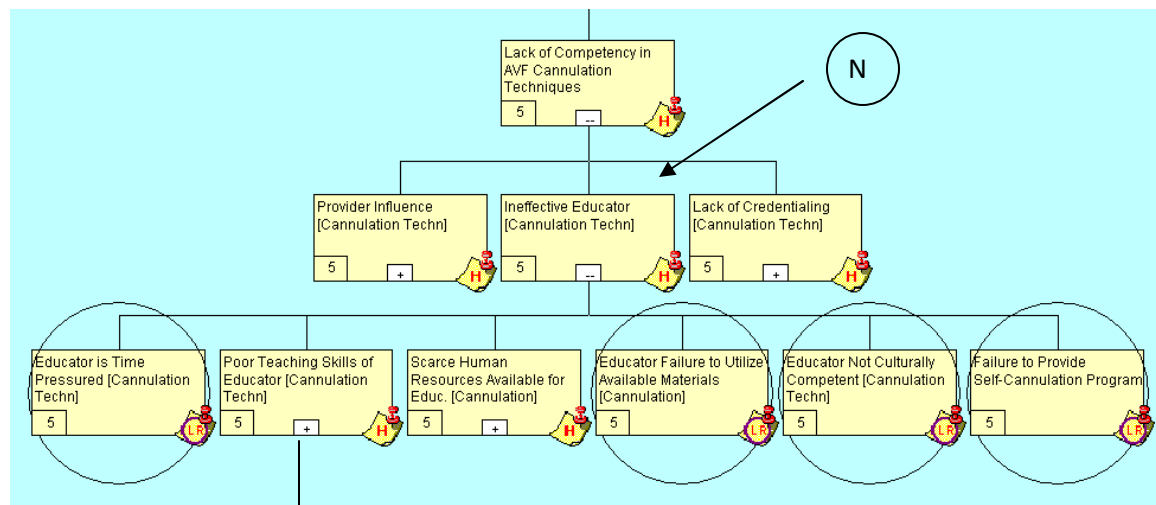


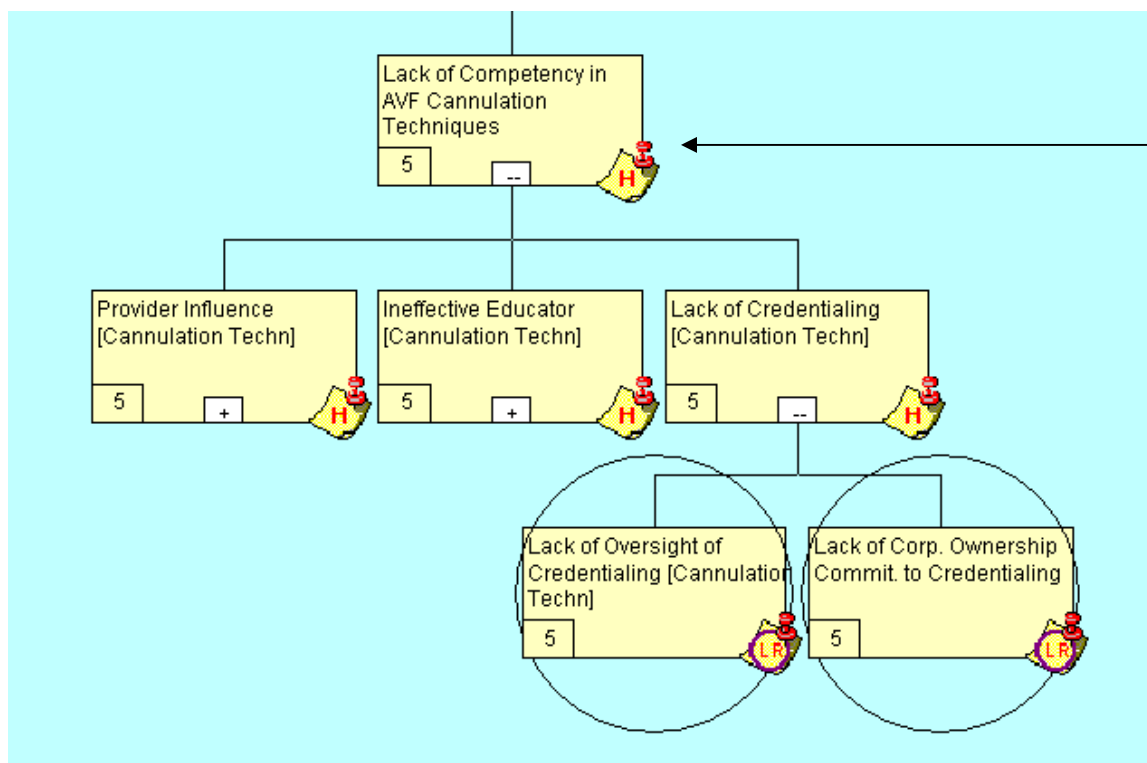
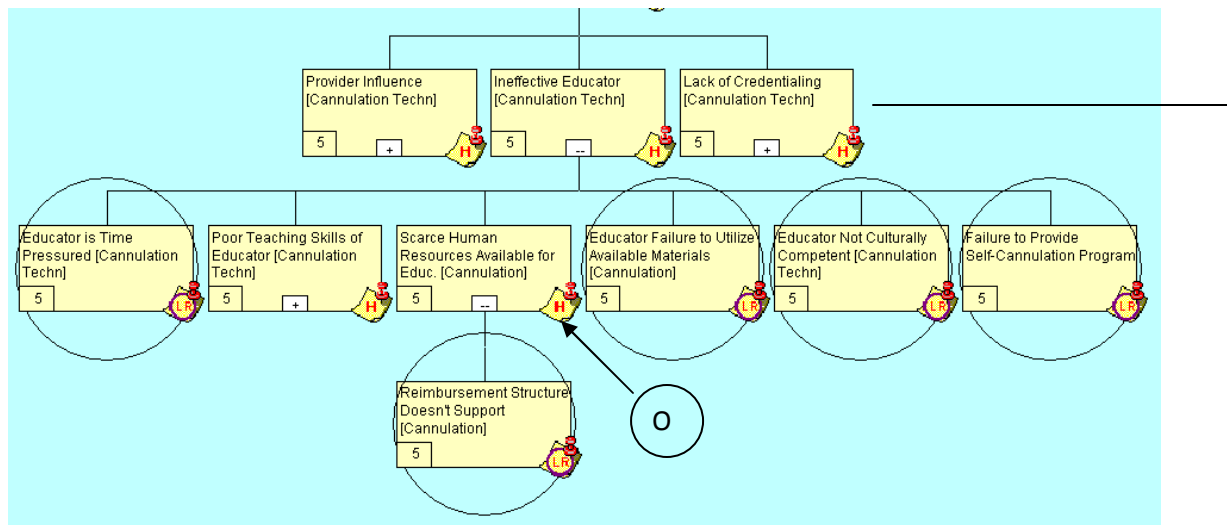


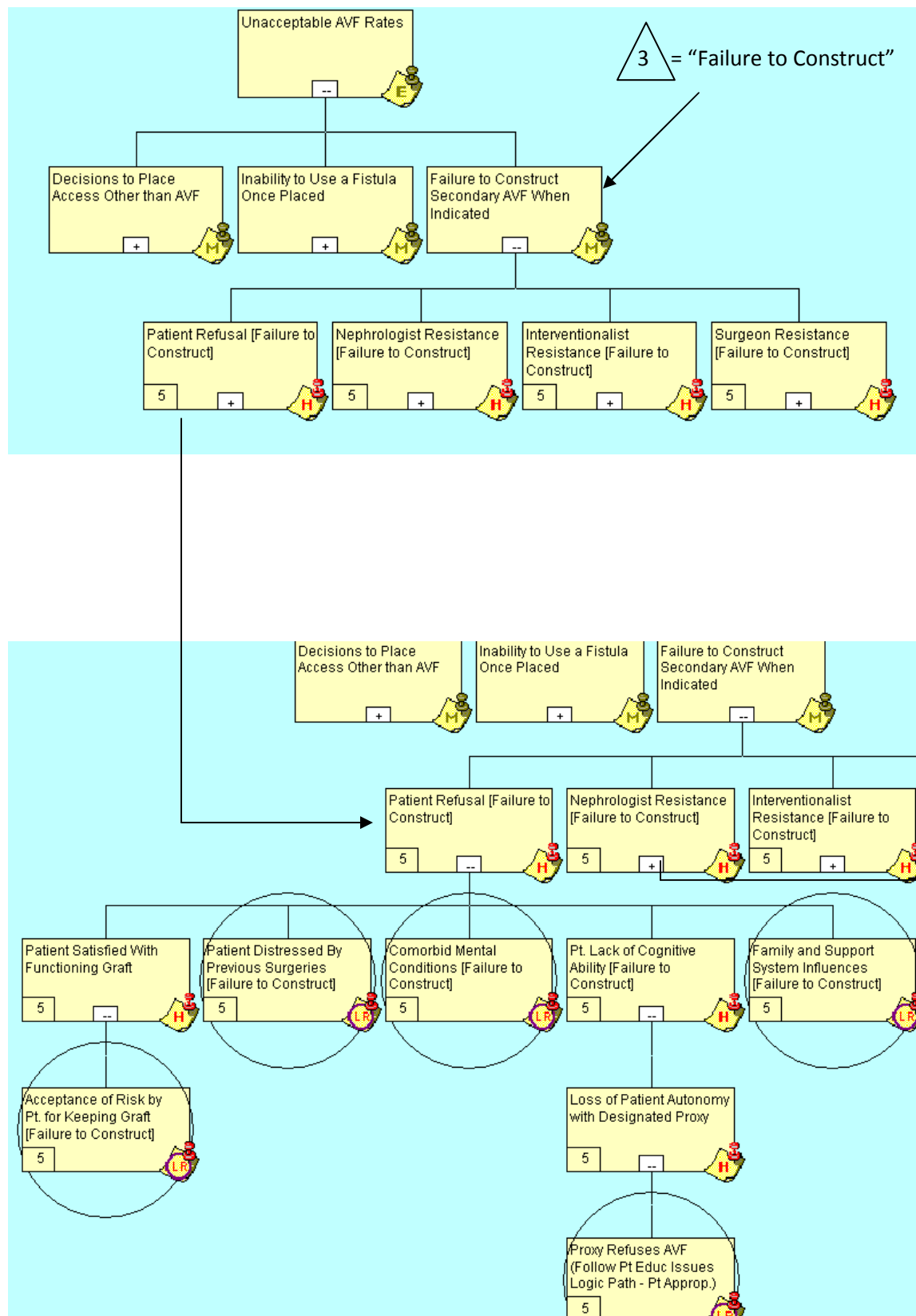


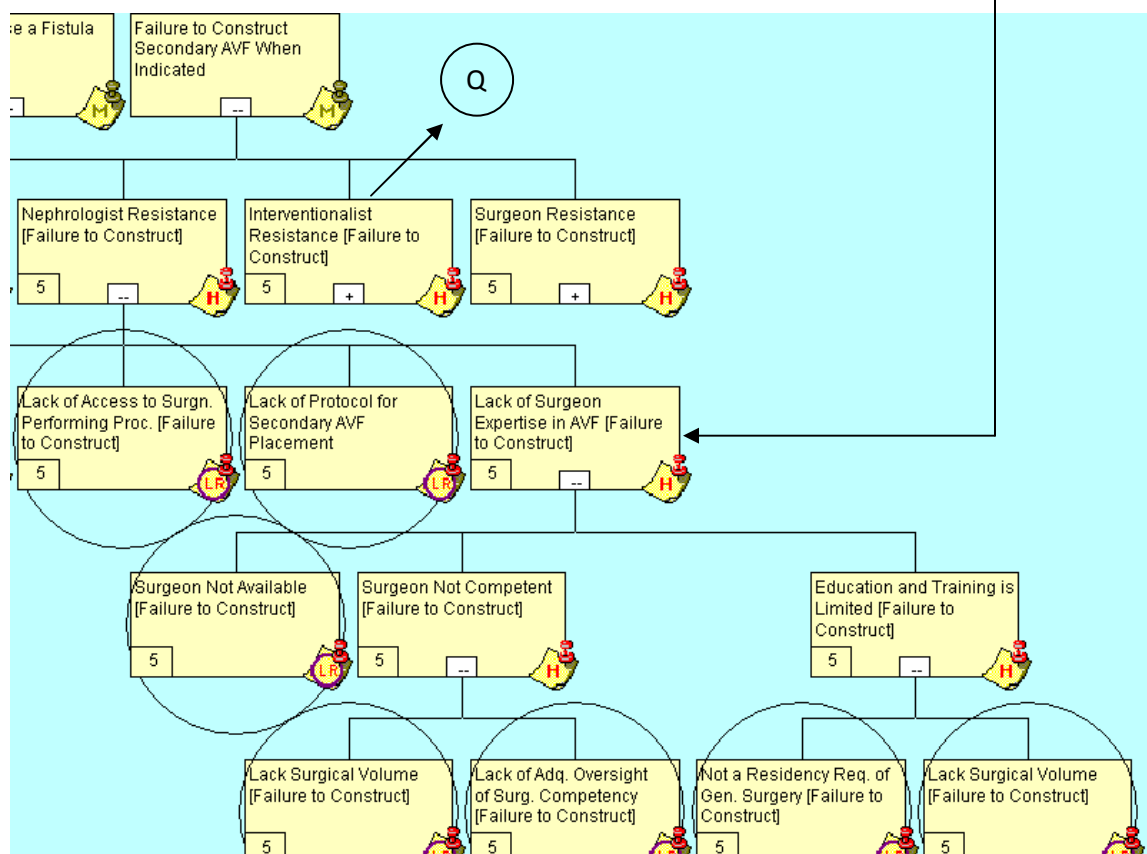
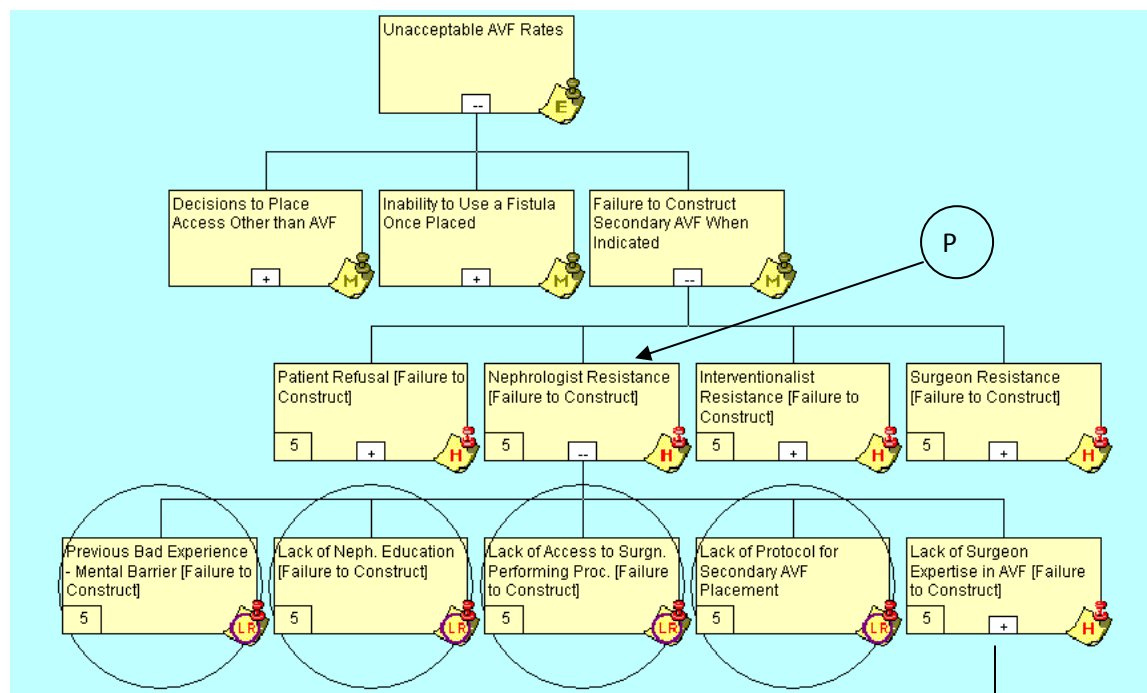












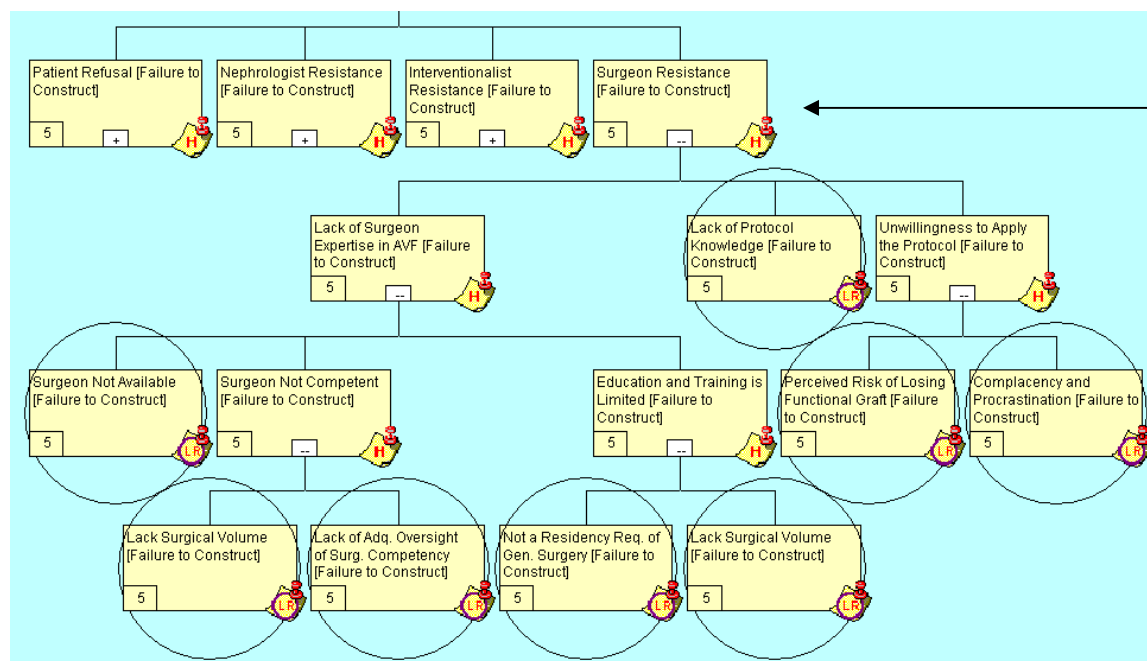
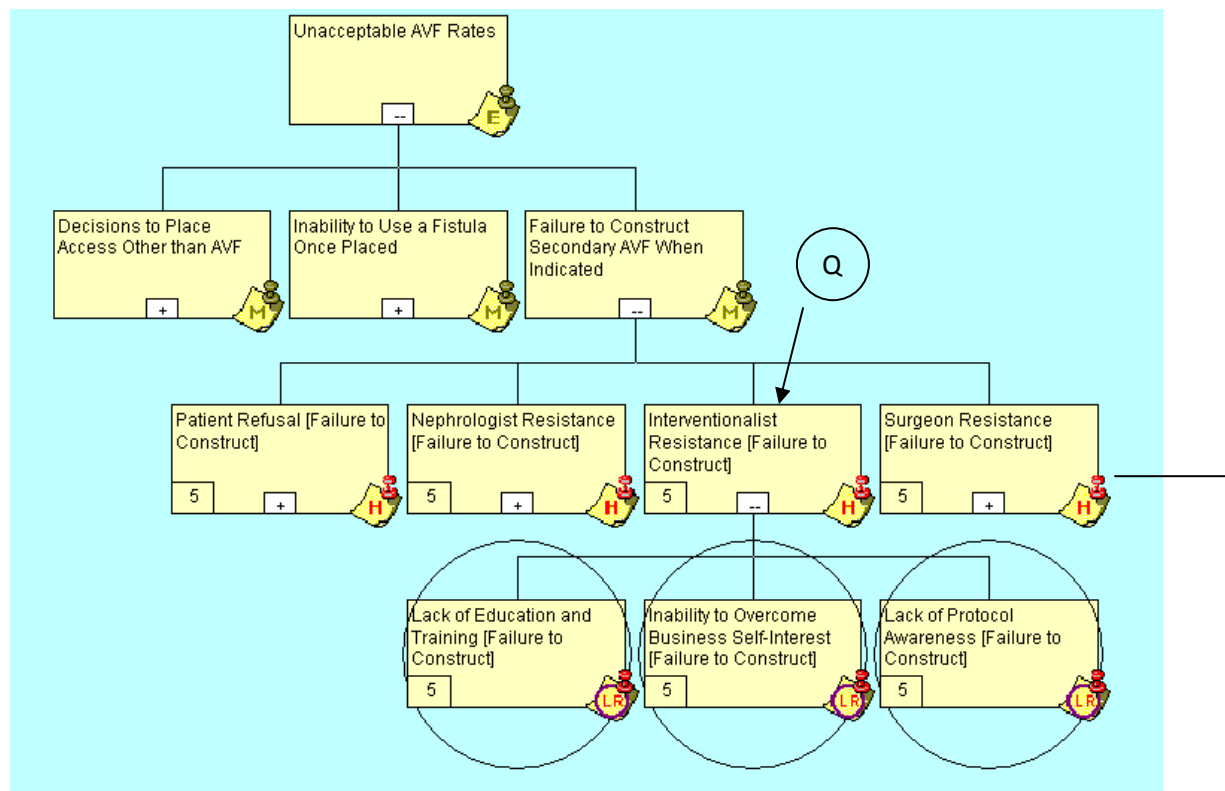


Exhibit 8a
Root Cause Analysis Full Cause Listing

			Decision to Place other than AV fistula	Sub Category	Relevant Change Concept
1	Education (11)	Patient refusal	Patient education content is not provided in all languages	Patient & Family	10
2	Education (11)	Patient refusal	Patient is not aware of educational materials that are available	Patient & Family	10
3	Education (11)	Patient refusal	Educator does not have time to educate patient	System	10
4	Education (11)	Patient refusal	Not seen as cost effective to provide proper supervisory oversight of patient education	System	10
5	Education (11)	Patient refusal	Establishing a patient education training program is not viewed as cost effective	System	10
6	Education (11)	Patient refusal	It's not viewed as cost effective to make an existing patient training program adequate	System	10
7	Education (11)	Patient refusal	Educator does not utilize patient education materials that are available	Knowledge Skills Perception	10
8	Education (11)	Patient refusal	Educator is not culturally competent, cannot relate to patient	Knowledge Skills Perception	10
9	Education (11)	Patient refusal	Reimbursement structure does not support patient education	Reimbursement Policy	10
10	Education (11)	Patient refusal	Patient has inadequate cognitive ability	Patient & Family	10
11	Education (11)	Patient refusal	Patient has health literacy issue	Patient & Family	10
12	Fears (2)	Patient refusal	Due to lack of patient education, patient is scared of surgery and/or needles	Patient & Family	10
13	Fears (2)	Patient refusal	Patient may suffer from mental illness	Patient & Family	10
14	Satisfaction (1)	Patient refusal	Patient is educated on risk of current access (catheter or graft) and is accepting of those risks	Patient & Family	10
15	Experience (3)	Patient refusal	Patient does not believe that the provider is "pro" AV fistula	Patient & Family	2,10

			Decision to Place other than AV fistula	Sub Category	Relevant Change Concept
16	Experience (3)	Patient refusal	Patient observes poor AV fistula cannulation techniques	Patient & Family	10,8
17	Experience (3)	Patient refusal	Patient perceives the AV fistula to be inconvenient compared to other accesses/ won't give up catheter	Patient & Family	10,7
18	Clinical Contraindication (3)	Physician decision	Physician believes patient has short life expectancy	Clinical Decision	2
19	Clinical Contraindication (3)	Physician decision	Physician believes the patient has inadequate vessels for AV fistula	Clinical Decision	2,3
20	Clinical Contraindication (3)	Physician decision	Physician views a vascular access induced ischemia prevents the use of an AV fistula	Clinical Decision	2,3
21	Surgeon (17)	Physician decision	Surgeon prefers AVG because of less post operative clinical care is required	Knowledge Skills Perception	5
22	Surgeon (17)	Physician decision	Surgeon believes that reputation is on the line if AV fistula fails	Knowledge Skills Perception	5
23	Surgeon (17)	Physician decision	Surgeon believes that AV fistulas have a negative impact on their schedules	Knowledge Skills Perception	5
24	Surgeon (17)	Physician decision	Surgeon is irritated by calls from other caregivers about AV fistulas	Knowledge Skills Perception	5
25	Surgeon (17)	Physician decision	Surgeon prefers AVG because there are no cannulation issues or problems	Knowledge Skills Perception	5
26	Surgeon (17)	Physician decision	AV fistula cost more and surgeon is not reimbursed for uninsured patients	Reimbursement Policy	5
27	Surgeon (17)	Physician decision	AV fistula takes more surgical time than an AVG but is reimbursed less	Reimbursement Policy	5
28	Surgeon (17)	Physician decision	Surgeon is not paid for post op time and more time is required for AV fistula	Reimbursement Policy	5
29	Surgeon (17)	Physician decision	Reduced payment for simultaneous procedures	Reimbursement Policy	5

			Decision to Place other than AV fistula	Sub Category	Relevant Change Concept
30	Surgeon (17)	Physician decision	Surgeon does not have AV fistula expertise	Knowledge Skills Perception	4,5
31	Surgeon (17)	Physician decision	Surgeon believes that AV fistula is technically harder to learn than AVG	Knowledge Skills Perception	5
32	Surgeon (17)	Physician decision	Surgeon does not believe that there is enough AV fistula volume to get comfortable with AV fistula creation	Knowledge Skills Perception	5
33	Surgeon (17)	Physician decision	There is no surgical competency oversight	Knowledge Skills Perception	4
34	Surgeon (17)	Physician decision	Surgeon is not competent because AV fistula is technically harder to learn	Knowledge Skills Perception	4,5
35	Surgeon (17)	Physician decision	AV fistula training is not required during residency for general surgery	Knowledge Skills Perception	5,10
36	Surgeon (17)	Physician decision	Training fails to have sufficient volume to get comfortable with AV fistula creation	Knowledge Skills Perception	5,10
37	Surgeon (17)	Physician decision	Surgeons receive biased information on AVG, manufacturers expanding indications beyond clinical appropriateness	Knowledge Skills Perception	5,10
38	Nephrologist (42)	Physician decision	Nephrologist does not want to deal with AV fistula problems	Knowledge Skills Perception	2,3
39	Nephrologist (42)	Physician decision	Nephrologist believes that surgeon does not have experience placing AV fistula	Knowledge Skills Perception	2,3
40	Nephrologist (42)	Physician decision	Nephrologist believes that AV fistulas do not mature because of the lack of surgical experience creating AV fistulas	Knowledge Skills Perception	2,3
41	Nephrologist (42)	Physician decision	Nephrologist believes that AV fistulas do not mature because there is inadequate vessel mapping	Knowledge Skills Perception	2,3
42	Nephrologist (42)	Physician decision	Nephrologist believes that AV fistulas do not mature because inappropriate clinical decisions were made due to inadequate vessel selection	Knowledge Skills Perception	2,3

			Decision to Place other than AV fistula	Sub Category	Relevant Change Concept
43	Nephrologist (42)	Physician decision	Nephrologist believes that AV fistulas do not mature because there is a failure of monitoring and surveillance	Knowledge Skills Perception	2
44	Nephrologist (42)	Physician decision	Nephrologist chooses surgeon based on reasons other than expertise	Political	4
45	Nephrologist (42)	Physician decision	Nephrologist lack of education on vascular access for sub groups (obese, elderly, etc.)	Knowledge Skills Perception	2,3
46	Nephrologist (42)	Physician decision	Nephrologist receives biased information on AVG and catheters, manufacturers expanding indications beyond clinical appropriateness	Knowledge Skills Perception	2,8
47	Nephrologist (42)	Physician decision	Nephrologist unwilling to talk to pre-CKD Stage 5 patients about their resistance to AV fistula	CKD 3-4	2
48	Nephrologist (42)	Physician decision	Nephrologist cannot identify when patient will have to start dialysis, creating a delayed decision by the patient	CKD 3-4	2,10
49	Nephrologist (42)	Physician decision	Nephrologist cannot convey the importance for AV fistula to the CKD Stage 5 patient	CKD 3-4	2,10
50	Nephrologist (42)	Physician decision	Nephrologist has to initiate patient on dialysis (urgent) before the patient has made a decision to get an AV fistula	CKD 3-4	2
51	Nephrologist (42)	Physician decision	Nephrologists believes patient has acute renal failure	Knowledge Skills Perception	2
52	Nephrologist (42)	Physician decision	Nephrologist unwilling to talk to prevalent CKD Stage 5 patients about their resistance to AV fistula	Knowledge Skills Perception	2
53	Nephrologist (42)	Physician decision	Patient education content is not provided in all languages	Patient & Family	10
54	Nephrologist (42)	Physician decision	Nephrologist is not aware of educational materials that are available	Knowledge Skills Perception	2,10
55	Nephrologist (42)	Physician decision	Educator is time pressured, covering a large geographic are in many cases	System	10

			Decision to Place other than AV fistula	Sub Category	Relevant Change Concept
56	Nephrologist (42)	Physician decision	Not seen as cost effective to provide proper supervisory oversight of staff education	System	10
57	Nephrologist (42)	Physician decision	Establishing a staff education training program is not viewed as cost effective	System	10
58	Nephrologist (42)	Physician decision	It's not viewed as cost effective to make an existing staff training program adequate	System	10
59	Nephrologist (42)	Physician decision	Reimbursement structure does not support staff education	Reimbursement Policy	10
60	Nephrologist (42)	Physician decision	Educator does not utilize patient education materials that are available	System	10,2
61	Nephrologist (42)	Physician decision	Educator is not culturally competent, cannot relate to patient	Knowledge Skills Perception	10,2
62	Nephrologist (42)	Physician decision	Patient has inadequate cognitive ability	Patient & Family	10,2
63	Nephrologist (42)	Physician decision	Patient has health literacy issue	Patient & Family	10,2
64	Nephrologist (42)	Physician decision	Family influences patient not to get AV fistula because of lack of education	Patient & Family	10,2
65	Nephrologist (42)	Physician decision	Due to lack of patient education, patient is scared of surgery and/or needles	Patient & Family	10,2
66	Nephrologist (42)	Physician decision	Patient fears needles because of comorbid mental illnesses	Patient & Family	10,2
67	Nephrologist (42)	Physician decision	Patient is educated on risk of current access (catheter or graft) and is accepting of those risks	Patient & Family	10,2
68	Nephrologist (42)	Physician decision	Patient does not feel that the provider is "pro" AV fistula	System	also 2
69	Nephrologist (42)	Physician decision	Patient observes poor AV fistula cannulation techniques	System	2,8
70	Nephrologist (42)	Physician decision	Patient perceives the AV fistula to be inconvenient compared to other accesses	Patient & Family	2,10
71	Nephrologist (42)	Physician decision	Patient has proxy who refuses AV fistula	Patient & Family	10

			Decision to Place other than AV fistula	Sub Category	Relevant Change Concept
72	Nephrologist (42)	Physician decision	Adequate cannulation training process of staff not viewed as cost effective by organization	System	also 2,8
73	Nephrologist (42)	Physician decision	Organizational pressure to reduce labor costs, adequate cannulation training not provided	System	also 2,8
74	Nephrologist (42)	Physician decision	Pressure for fast turnover, faster to turnover catheter patients then AV fistula patients	System	2,7
75	Nephrologist (42)	Physician decision	Pressure for fast turnover, faster to turnover catheter patients then AV fistula patients helps reduce labor costs	System	2,7
76	Nephrologist (42)	Physician decision	Lack of RN education because of organizations focus on short term profits	System	2,10
77	Nephrologist (42)	Physician decision	Lack of RN education because of pressure to reduce labor cost	System	2,10
78	Nephrologist (42)	Physician decision	Lack of tech education because of organizations focus on short term profits	System	2,10
79	Nephrologist (42)	Physician decision	Lack of tech education because of pressure to reduce labor costs	System	2,10
80	Interventionalists (7)	Physician decision	Interventionalist does not perceive advantage of AV fistula due to failure to properly utilize vessel mapping	Knowledge Skills Perception	10,9
81	Interventionalists (7)	Physician decision	Interventionalists failure to follow KDOQI because they do not see the advantage of AV fistula	Knowledge Skills Perception	10,9
82	Interventionalists (7)	Physician decision	Interventionalist does not refer to surgeon as the KDOQI guidelines suggest	Knowledge Skills Perception	10,9
83	Interventionalists (7)	Physician decision	Interventionalist believes that there is an economic disincentive to refer to surgeons if they were to follow the KDOQI guidelines	Knowledge Skills Perception	10,9
84	Interventionalists (7)	Physician decision	Interventionalist lacks knowledge on Fistula First guidelines and does not see the advantage of AV fistula	Knowledge Skills Perception	10,9
85	Interventionalists (7)	Physician decision	Interventionalist does not refer to surgeon as the Fistula First guidelines suggest	Knowledge Skills Perception	10,9

			Decision to Place other than AV fistula	Sub Category	Relevant Change Concept
86	Interventionalists (7)	Physician decision	Interventionalist believes that there is an economic disincentive to refer to surgeons if they were to follow Fistula First guidelines	Knowledge Skills Perception	10,9
87	Vessel Non-preservation (9)		Failure to educate non-nephrologist on acute care setting on vessel preservation with detection of CKD 3-5	CKD 3-4	10,2
88	Vessel Non-preservation (9)		Failure to educate non-nephrologist in outpatient setting on vessel preservation with detection of CKD 3-5	CKD 3-4	10,2
89	Vessel Non-preservation (9)		The lack of an adequate computer flagging system there is a failure to detect CKD 3-5	CKD 3-4	1,10
90	Vessel Non-preservation (9)		Inadequate use of discharge planning there is a failure to detect CKD 3-5	CKD 3-4	1,10
91	Vessel Non-preservation (9)		Failure to educate patients on vessel preservation	CKD 3-4	10
92	Vessel Non-preservation (9)		Over utilization of PICC lines	CKD 3-4	1,10
93	Vessel Non-preservation (9)		Failure to educate PCPs on vascular access/vessel preservation	CKD 3-4	1,2,10
94	Vessel Non-preservation (9)		Failure to influence on vascular access/vessel preservation	CKD 3-4	1,2,10
95	Vessel Non-preservation (9)		Failure for nephrology to approve all PICC lines with GFR less than 45	CKD 3-4	2,10
Inability to Use Once Placed					
96	Failure to Mature (2)	Failure to properly use procedure for AV fistula not maturing	Fail to Use Endovascular Procedures	Knowledge Skills Perception	9
97	Failure to Mature (2)	Failure to properly use procedure for AV fistula not maturing	Fail to surgically revise when Indicated	Knowledge Skills Perception	9
98	Failure to Monitor (5)	Failure to monitor development of AV fistula	Not viewed as cost effective to the organization	System	9

			Inability to Use Once Placed	Sub Category	Relevant Change Concept
99	Failure to Monitor (5)	Failure to monitor development of AV fistula	Patient lacks transportation to get to surgeon	Patient & Family	9
100	Failure to Monitor (5)	Failure to monitor development of AV fistula	Patient and surgeon scheduling conflicts	System	9
101	Failure to Monitor (5)	Failure to monitor development of AV fistula	No surgical follow up appointment made	System	9
102	Failure to Monitor (5)	Failure to monitor development of AV fistula	Patient refuses to go to surgeon	Patient & Family	9
103	Cannulation (12)	Lack of competency in AV fistula cannulation	Organizational Focus on Short Term Profits - Productivity Mentality	System	8
104	Cannulation (12)	Lack of competency in AV fistula cannulation	Organizational Pressure to reduce labor costs	System	8
105	Cannulation (12)	Lack of competency in AV fistula cannulation	Educator is time pressured, covering a large geographic area and many facilities	System	8
106	Cannulation (12)	Lack of competency in AV fistula cannulation	Educator is not culturally competent and cannot communicate with patient	Knowledge Skills Perception	8
107	Cannulation (12)	Lack of competency in AV fistula cannulation	No provision for self-cannulation training available	System	8
108	Cannulation (12)	Lack of competency in AV fistula cannulation	Teaching Skills of Educator lacking due to not being viewed as cost effective	System	8
109	Cannulation (12)	Lack of competency in AV fistula cannulation	Adequate training process of educator viewed by organization as not cost effective	System	8
110	Cannulation (12)	Lack of competency in AV fistula cannulation	Establishing a training program for educators is not viewed as cost effective	System	8

			Inability to Use Once Placed	Sub Category	Relevant Change Concept
111	Cannulation (12)	Lack of competency in AV fistula cannulation	Scarce human resource available due to current reimbursement structure	Reimbursement Policy	8
112	Cannulation (12)	Lack of competency in AV fistula cannulation	Educator fails to use available resources	Knowledge Skills Perception	8
113	Cannulation (12)	Lack of competency in AV fistula cannulation	Lack of organizational ownership and commitment to cannulation credentialing	System	8
114	Cannulation (12)	Lack of competency in AV fistula cannulation	Lack of organizational oversight to cannulation credentialing	System	8
Failure to Construct Secondary AV fistula					
115	Patient (5)	Patient refusal	Patient satisfied with graft/catheter and accepting risk	Patient & Family	6
116	Patient (5)	Patient refusal	Patients medical comorbid medical conditions interfere with placement	Patient & Family	6
117	Patient (5)	Patient refusal	Family/support systems influences patient to not have AV fistula placed	Patient & Family	6
118	Patient (5)	Patient refusal	Comorbid mental conditions limit patients ability to understand and consent	Patient & Family	6
119	Patient (5)	Patient refusal	Patient lacks cognitive ability to make decision and proxy refuses AV fistula placement	Patient & Family	6
120	Nephrologist (9)	Nephrologist resistance	Previous bad experience with AV fistula - Mental Barrier	Knowledge Skills Perception	6
121	Nephrologist (9)	Nephrologist resistance	Lack of education related to AV fistula placement	Knowledge Skills Perception	6
122	Nephrologist (9)	Nephrologist resistance	Lack of access to surgeon who performs AV fistula placement	System	6
123	Nephrologist (9)	Nephrologist resistance	Lack of protocol for secondary AV fistula placement	Knowledge Skills Perception	6

			Failure to Construct Secondary AV fistula	Sub Category	Relevant Change Concept
124	Nephrologist (9)	Nephrologist resistance	Surgeon not competent to perform AV fistula placement due to lack of surgical volume	Knowledge Skills Perception	6
125	Nephrologist (9)	Nephrologist resistance	Surgeon not competent to perform AV fistula placement due to lack of surgical competency oversight	Knowledge Skills Perception	6
126	Nephrologist (9)	Nephrologist resistance	Education and training limited because of lack of surgical volume	Knowledge Skills Perception	6
127	Nephrologist (9)	Nephrologist resistance	AV fistula education and training not part of General Surgery residency requirements	Knowledge Skills Perception	6
128	Nephrologist (9)	Nephrologist resistance	Lack of surgeon in area to perform AV fistula placement	System	6
129	Interventionalist (3)	Interventionalist resistance	Inability to overcome business self interest	Political	6
130	Interventionalist (3)	Interventionalist resistance	Lack of education and training related to FF	Knowledge Skills Perception	6
131	Interventionalist (3)	Interventionalist resistance	Lack of awareness of protocol for AV fistula placement	Knowledge Skills Perception	6
132	Surgeon (8)	Surgeon resistance	AV fistula education and training not part of General Surgery residency requirements	Knowledge Skills Perception	6
133	Surgeon (8)	Surgeon resistance	Surgeon not competent to perform AV fistula placement due to lack of surgical competency oversight	Knowledge Skills Perception	6
134	Surgeon (8)	Surgeon resistance	Surgeon not competent to perform AV fistula placement due to lack of surgical volume	Knowledge Skills Perception	6
135	Surgeon (8)	Surgeon resistance	Education and training limited because of lack of surgical volume	Knowledge Skills Perception	6
136	Surgeon (8)	Surgeon resistance	Lack of awareness of protocol for AV fistula placement	Knowledge Skills Perception	6

			Failure to Construct Secondary AV fistula	Sub Category	Relevant Change Concept
137	Surgeon (8)	Surgeon resistance	Unwilling to apply protocol related to perceived risk of losing functioning graft	Knowledge Skills Perception	6
138	Surgeon (8)	Surgeon resistance	Surgeon unavailable in area to place AV fistula	System	6
139	Surgeon (8)	Surgeon resistance	Unwilling to apply protocol related to complacency and procrastination	Knowledge Skills Perception	6

Appendix B

Fistula First Change Package

Fistula First Change Package

Clinical and organizational recommendations based on best practices for increasing AV fistula use and improving hemodialysis patient outcome

1 Routine CQI review of vascular access

- Designate staff member in dialysis facility responsible for vascular access CQI (RN if feasible but can be any renal care professional). Incorporate vascular access into facility-based CQI process.
- Assemble multi-disciplinary vascular access CQI team in facility or hospital.
 - Minimally: Medical Director and VA CQI Coordinator.
 - Ideally: Representatives of all disciplines, including access surgeons and interventionalists.
- Investigate and track all non-AV fistula access placements and AV fistula failures.

2 Timely referral to nephrologist

- Primary care physicians utilize pre-ESRD/CKD referral criteria to ensure timely referral of patients to nephrologists, ideally prior to Stage 4 CKD.
 - Establish meaningful criteria for PCPs who may not perform GFR or creatinine clearance testing (i.e. serum creatinine criteria, conversion formula for GFR)
- Nephrologist documents AV fistula plan for all patients expected to require renal replacement therapy, regardless of RRT being considered.
- Designated nephrology staff person educates patient and family on benefits of AV fistula and to protect vessels, when possible using bracelet as reminder.

3 Early referral to surgeon for “AV fistula only” evaluation and timely placement

- Nephrologist/skilled nurse performs appropriate evaluation and physical exam prior to surgery referral.
- Nephrologist refers for vessel mapping where feasible, ideally prior to surgery referral.
- Nephrologist refers patients to surgeons for “AV fistula only” evaluation, no later than Stage 4 CKD (GFR<30). Surgery scheduled with sufficient lead-time for AV fistula maturation.
- Nephrologist defines AV fistula expectations to surgeon, including vessel mapping.
- If pre-ESRD placement of AV fistula does not occur, nephrologist ensures that patient receives AV fistula evaluation and placement (if feasible) at the time of initial hospitalization for temporary access (e.g. catheter).

4 Surgeon selection based on best outcomes, willingness, and ability to provide access services

- Nephrologists communicate expectations to surgeons regarding AV fistula placement and training in current AV fistula surgical techniques, based on K/DOQI Guidelines and best practices.
- Nephrologists refer to surgeons willing and able to meet AV fistula expectations based on K/DOQI and best practices.
- Surgeons are continuously evaluated on frequency, quality, and patency of access placements. Data collection and outcomes tracking ideally initiated and reported at the dialysis center as part of ongoing CQI process, and can be aggregated at the Network level.

5 Full range of appropriate surgical approaches to AV fistula evaluation and placement

- Surgeons utilize current techniques for AV fistula placement including vein transpositions.
- Surgeons ensure mapping is performed for any patient candidate not deemed suitable for AV fistula based solely on physical exam.

6 Secondary AV fistula placement in patients with AV grafts

- Nephrologists evaluate every AV graft patient for possible secondary AV fistula, including mapping as indicated, and document plan in patient's record.
- Dialysis facility staff and/or rounding nephrologists examine outflow vein of all forearm graft patients ("sleeves up") during dialysis treatments (minimum frequency=monthly) to identify patients who may have suitable upper outflow vein for elective secondary AV fistula conversion in upper arm. Inform nephrologist and surgeon of need to evaluate identified outflow vein for AV fistula conversion.
- Nephrologist refers to surgeon for evaluation/placement of secondary AV fistula before failure of AVG.

7 AV fistula placement in patients with catheters where indicated

- Regardless of prior access (e.g. AV graft), nephrologists and surgeons evaluate all catheter patients as soon as possible for AV fistula, including mapping as indicated.
- Facility implements protocol to track all catheter patients for early removal of catheter.
- Nephrologists make every effort not to admit patients to clinic with "catheter only"

8 Cannulation training for AV fistulas

- Facility identifies and uses best cannulators and best teaching tools (e.g., videos) to teach AV fistula cannulation to all appropriate dialysis staff.
- Dialysis staff uses specific protocol for initial dialysis treatments with new AV fistulas and assigns the most skilled staff to such patients.
- Facility offers option of self-cannulation to patients who are interested and able.

9 Monitoring and maintenance to ensure adequate access function

- Nephrologists and surgeons conduct post-operative physical evaluation of AV fistulas in 4 weeks to detect early signs of failure and refer for diagnostic study and remedial intervention as indicated.
- Facilities adopt standard procedures for monitoring, surveillance, and timely referral for the failing AV fistula.
- Nephrologists, interventional radiologists, and surgeons adopt standard criteria, and a plan for each patient, to determine the appropriate extent of intervention on an existing access before evaluating and mapping for an AV fistula.

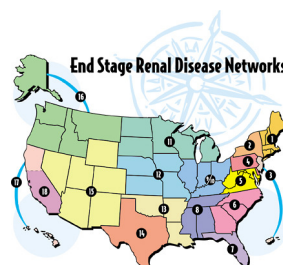
10 Education for care givers and patients

- Routine facility staff in-servicing and education program in vascular access.
- Continuing education for all caregivers to include periodic in-services by nephrologists, surgeons, and interventionalists.
- Facilities educate patients to improve quality of care and outcomes (e.g., prepping puncture sites, applying proper pressure at needle sites without clamps, AV fistula brochures, etc.).

11 Outcomes feedback to guide practice

- Networks work with dialysis providers to provide specific outcomes feedback to all decision-makers, including incident and prevalent rates of AV fistula, AVG, and catheter use.
- Review data monthly or quarterly in facility staff meetings. Discuss and evaluate data trended over time for incident and prevalent rates of AV fistula, AVG, and catheter use. Track and disseminate all vascular access-related outcomes.

For further information, contact your ESRD Network. A complete listing of ESRD Networks can be found at: <http://www.esrdnetworks.org/>. *Fistula First* is an initiative of the Centers for Medicare and Medicaid Services and the Department of Health and Human Services. Project assistance provided by the Institute for Healthcare Improvement.



Appendix C

Fistula First RCA Verification Log Bibliography

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Appendix D

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