SCOTT & WHITE HEALTHCARE/SWHP
TECHNOLOGY ASSESSMENT
OVERVIEW & INTRODUCTION

The Scott & White HealthCare (SWHC) and Scott & White Health Plan (SWHP) Technology Assessment Committee evaluates the clinical efficacy, safety, cost, and fee information for new, replacement or uncovered medical and behavioral procedures, treatments, devices or equipment. This assessment is used to evaluate not only the efficacy, safety, and cost effectiveness of the new procedures, devices or treatments, but also for consideration for coverage under SWHP and review of other coverage determinations made by other major insurors.

The current standing committee consists of the Scott and White Memorial Hospital (SWMH) Chief Medical Officer, SWHP Chief Medical Officer, SWHP Medical Directors, SWHC Chief Executive Officer, SWHC Chief Operation Officer, SWHC Chief Medical Officer, SWHC Chief Quality Officer, SWHC Associate Chief Medical Officer, SWHP Medical Director for System Improvement, SWHC Chairman of Department of Medicine, SWHC Chairman of Department of Orthopedic Surgery, SWHC Chairman of Department of Surgery, Hillcrest Baptist Medical Center Chief Medical Officer and Executive Vice President, Scott and White HealthCare - Round Rock Chief Medical Officer, Scott and White HealthCare - Brenham - Chief Medical Officer, SWMH Chief Nursing Executive, Scott and White HealthCare Vice President, Quality, Safety and Regulatory Services, SWHC Chief Financial Officer, SWHC Vice President, Pharmacy Services, SWHC Director of Supply Chain Services, SWHC Vice President, Managed Care / Financial Planning, SWHC Vice President Revenue Cycle Operations Hospital Division, SWMH Chief Nursing Officer/Chief Operating Officer, and SWHP Associate Vice President - Medical Services.

The Technology Assessment Committee requests that you (the Provider that is most directly involved and/or appears to be the one that will use the technology under assessment), to complete the attached forms and analysis for their consideration during the technology/new procedure assessment.

Information and/or questions to be submitted to:
Debbie Garrett, Director of Health Services, SWHP
Phone/email 254-298-3085/ degarrett@.sw.org

There are five separate tabs in this Excel workbook, and please complete all required information. Dynamic links to separate tabs for 4 of the 5 pages are as follows:

Checklist

New Procedure Form

Additional Information (not hyperlinked)

FMEA Worksheet

FMEA Training Tool

The completed forms and other supporting information are to be timely submitted electronically or via mail to Debbie Garrett a minimum of ten business days prior to the scheduled Technology Assessment Committee meeting.

LAST DATE REVISED/UPDATED 10/1/2012
DATE LAST TAC COMMITTEE REVIEWED/APPROVED 10/31/2012
DATE LAST UM COMMITTEE REVIEWED/APPROVAL
DATE LAST QIS COMMITTEE REVIEW/APPROVAL

SCOTT & WHITE HEALTHCARE/SWHP
TECHNOLOGY ASSESSMENT
CHECKLIST OF INFORMATION AND
ANALYSIS REQUIRED

	DONE
1 Scott and White Health Plan (SWHP)TAC will utilize evidence-based reports from Haye's Technology Assessment, Inc. for review analysis and recommendations regarding SWHPcoverage determinations. If Haye's does not have a review, the requesting physician/specialty service will be required to submit a minimum of three well-designed and well-conducted clinical investigations published in peer review journals to include:	☐
o Medical evidence to support that the new technology can measure or alter the physiologic changes related to disease, illness or condition.	
o Medical evidence that based upon medical facts, the new technology positively affects the health outcome of the patient.	
2 Completion of the New Procedure Form and Required General Information Sections .	☐
3 Completion of the FMEA worksheet, if applicable.	☐
4 Submit completed forms and other supporting information to Debbie Garrett, Director of Health Services, SWHP electronically or in the mail at a minimum of 10 business days prior to the scheduled Technology Assessment Committee Meeting.	☐

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NEW PROCEDURE FORM

1/17/2013 7:07

NOTE: Please enter information on lines or shaded areas provided. Should additional space be needed, please make reference to attached information.

Name of procedure(medical/surgical) or behavioral health treatment/technology/device/equipment (Enter on New Procedure Form):

ENTER NAME ON NEW PROCEDURE FORM

Name of Department (Individual and/or Group) making the application:

ENTER DEPT ON NEW PROCEDURE FORM

	Please Check One	
	YES	NO
1 Has the procedure been used elsewhere?	☐	☐

If YES, please include details here:

	YES	NO
2 Does this new procedure replace current procedures?	☐	☐

If YES, please include details here:

	YES	NO
3 If YES to 2, does the new procedure have advantages over the current procedures?	☐	☐

If YES, please include details here:

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NEW PROCEDURE FORM

1/17/2013 7:07

	Please Check One	
	YES	NO
4 Has the procedure been evaluated elsewhere?	☐	☐

If YES, please include details here:

If YES, please attach and list a minimum of three clinical investigations conducted in peer reviews:

	YES	NO
5 If the procedure involves the use of a new medical device, has the device been approved for this purpose by the following (Refer to additional device questions at number 11):		
FDA	☐	☐
Medicare	☐	☐
Other:	☐	☐
Other:	☐	☐

Please attach support.

	YES	NO
6 Are there any training requirements for the proposed new procedure or equipment?	☐	☐

If YES, please include details here:

		Please Check One	
7	**Has a patient information or education sheet and/or plan been developed?**	**YES** ☐	**NO** ☐

If YES, please attach support.

8 How will outcomes be monitored?

Please include details here:

		Please Check One	
9	**If the procedure carries with it a risk for adverse events are there criteria for reviewing outcomes before further procedures are performed?**	**YES** ☐	**NO** ☐

If YES, please complete FMEA WORKSHEET and include other details here:
Link to FMEA Worksheet here:

		Please Check One	
10	**Is there any additional follow-up care required for the new procedure?**	**YES** ☐	**NO** ☐

If YES, please include details here:

11 **As discussed in 5, if this new procedure includes a new medical device (product), briefly describe this product:**

12	**Is there a current in-house product now performing the same function or procedure?**	**YES** ☐	**NO** ☐

If YES, please include details here:

		Please Check One	
		YES	NO
13	**Will the requested new product replace or supplement current in-house products?**	☐	☐

If YES, please include details here:

		YES	NO
14	**What other departments will use or be affected by this product?**	☐	☐

Please include details here:

		YES	NO
15	**Are there resident & other training education issues to consider for approving this procedure/device?**	☐	☐

Please include details here:

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ADDITIONAL INFORMATION

Are other payors providing coverage for this new procedure/treatment? If so, who and under what terms?	
Are there any facts not provided elsewhere in this format that you wish to highlight to the Committee regarding your coverage request?	
Please include any known CPT/HCPCS and/or associated billing codes	
Please provide some idea of the cost for the new product, device, drug, service, procedure, etc. under review	
Please provide any comparative costs for current similar services, devices, etc.	

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FMEA WORKSHEET

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Note: Refer to FMEA Training Tool Tab for more information regarding the FMEA Worksheet.

Process:	
Specific Process Step:	
Date Revised:	
Severity	**1: no effect on output, 5:moderate effect, 8: serious effect, 10: hazardous effect**
Occurrence	**1: failure unlikely, 5: occasional failure, 8: high # of failures likely, 10: failures certain**
Detection	**1: will detect failure, 5: might detect failure, 10: almost certain not to detect failures**
RPN =	**Severity Rating x Occurrence Rating x Detection Rating**

										Action Results				
Failure Mode	Effects of Failure	SV	Causes of Failure	OC	Current Controls	DT	RPN	Actions	Resp & Target Date	Action Taken	SV	OC	DT	RPN

SCOTT & WHITE HEALTHCARE/SWHP
TECHNOLOGY ASSESSMENT

Failure Mode and Effect Analysis (FMEA): ***Training Tool***

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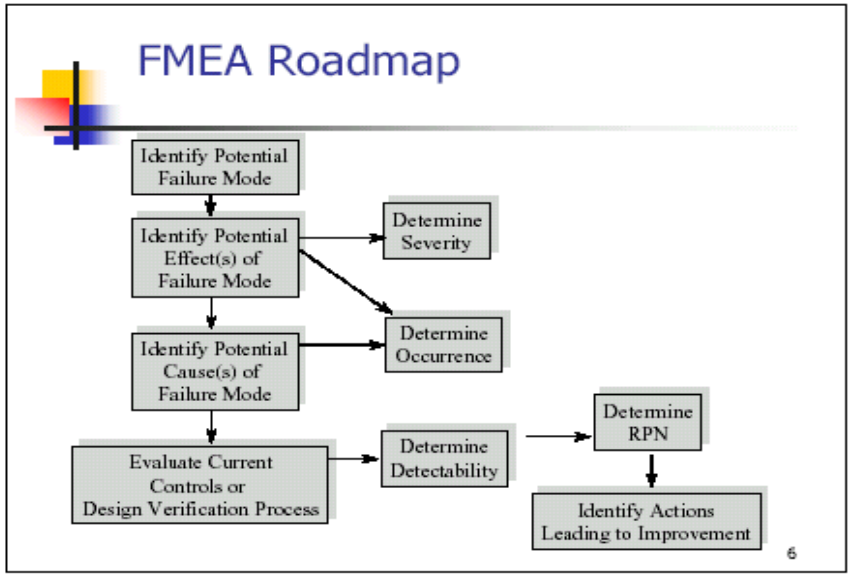
What's an "FMEA"?

An FMEA (failure mode and effect analysis) is the structured analysis of a system or process with the intent to prevent failures ***prior to*** their occurring, and documents the actions taken by an organization to minimize the risks of failures.

In an FMEA, each individual failure is considered as an independent occurrence with no relation to other failures in the system. FMEA's identify single failure modes that either directly result in or contribute significantly to an accident.

The general steps within a simple FMEA are:

- Identifying the role of each component in process (a "functional analysis")
- Identifying each type or mode of failure
- Identifying the causes & effects of each failure
- Identifying existing safeguards/controls against the failure
- Prioritize actions leading to improvement



Adapted from:http://www.fmeainfocentre.com

Goal

Through use of the FMEA method, our goal is to identify actions needed to improve the selected "process" we focus on.

Specific Steps in the FMEA Analysis

PHASE 1

1 Identifying a system, operation, or process to analyze
2 Identifying each step or part of the process. (Typically a flow chart)
3 Identifying the role or function of each of the process steps (This is called a "functional analysis" – using a separate FMEA worksheet to analyze each process step).
4 Identifying the potential or known failures that may occur at each step. Failure modes typically occur when a function is not performed.
5 Identifying the effects of each failure mode.
6 Identifying the causes of each failure mode.
7 Prioritizing the identified failure modes based on the frequency of occurrence (OC).
8 Prioritizing the identified failure modes based on severity (SV).
9 Prioritizing the identified failure modes based on the likelihood of detection (DT) with existing controls.
10 Calculation of a Risk Priority Number (using items 7, 8, & 9)
11 Providing for follow-up corrective and preventive actions, prioritized by Risk Priority Number, with an assigned person.
12. Re-analysis of Risk Priority Number after actions are taken ("action results").

Completing the FMEA Worksheet – First 8 columns only

Column 1: FAILURE MODE
Describe what kind of failures might occur. Begin with a “failure” of skipping the step entirely. Consider other failures such as incomplete performance of the step, or inaccurate completion of the step. Think about the failures that could be the most severe first. Also, think about failures that might commonly occur. (free text)

Column 2: EFFECTS OF FAILURE
What are the initial results of this failure? The end results if not caught? (free text)

Column 3: SEVERITY
How severe of an effect is that, on a 1-10 scale?

Severity is a rating corresponding to the seriousness of an effect of a potential failure mode. (scale: 1-10. 1: no effect on output, 5: moderate effect, 8: serious effect, 10: hazardous effect)

Column 4: CAUSES OF FAILURE
What are the common causes of this failure? (free text)

Column 5: OCCURRENCE
How often is this failure likely to occur, on a 1-10 scale?

Occurrence is a rating corresponding to the rate at which a first level cause and its resultant failure mode will. (scale: 1-10. 1: failure unlikely, 5: occasional failure, 8: high # of failures likely, 10: failures certain)

Column 6: CURRENT CONTROLS/SAFEGURDS
Describe what processes (controls or safeguards) we have in place to detect this failure before it reaches the patient. Safeguards are the equipment, procedures, and administrative controls in place to help (1) prevent the failure from occurring or (2) lessen the effects if the situation does occur. (free text)

Column 7: DETECTION/FAIL DETECTION

How likely are current controls to detect the failure, on a 1-10 scale?

Detection is a rating corresponding to the likelihood that the detection methods or current controls will detect the potential failure mode before the process reaches the patient (scale: 1-10. 1: will detect failure, 5: might detect failure, 10: almost certain not to detect failures)

Column 8: Calculating Risk Priority Number (RPN)
The RPN identifies the greatest areas of concern.
It comprises the assessment of the:
(1) Severity rating,
(2) Occurrence rating, and
(3) detection rating for a potential failure mode.

RPN = Severity Rating x Occurrence Rating x Detection Rating
The highest possible RPN is 10 x 10 x 10 =1000

Guidelines for Applying 1-10 Rank Scores for Severity, Occurrence, & Detection

SEVERITY (S)

Effect	Ranking
Hazardous without warning	10
Hazardous with warning	9
Very High	8
High	7
Moderate	6
Low	5
Very Low	4
Minor	3
Very Minor	2
None	1

Occurrence (O)

Probability of Failure	Possible Failure Rates	Ranking
Very High: Failure is almost inevitable	≥1 in 2	10
	1 in 3	9
High: Repeated Failures	1 in 8	8
	1 in 20	7

Moderate: Occasional Failures	1 in 80	6
	1 in 400	5
	1 in 2,000	4
Low: Relatively Few Failures	1 in 15,000	3
	1 in 150,000	2
Remote: Failure is Unlikely	≤1 in 1,500,000	1

Detection (D)

Detection	Criteria: Likelihood of Detection by Design Control	Ranking
Absolute Uncertainty	Current controls will not and/or cannot detect a potential cause/mechanism and subsequent failure mode; or there is no Design Control.	10

Very Remote	Very remote chance the current controls will detect a potential cause/mechanism and subsequent failure mode.	9
Remote	Remote chance the current controls will detect a potential cause/mechanism and subsequent failure mode.	8
Very Low	Very Low chance the current controls will detect a potential cause/mechanism and subsequent failure mode.	7
Low	Low chance the current controls will detect a potential cause/mechanism and subsequent failure mode.	6

Moderate	Moderate chance the current controls will detect a potential cause/mechanism and subsequent failure mode.	5
Moderately High	Moderately high chance the current controls will detect a potential cause/mechanism and subsequent failure mode.	4
High	High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	3
Very High	Very High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode	2

Almost Certain	Design Control will almost certainly detect a potential cause/mechanism and subsequent failure mode	1