Skin biopsy

Identifying and overcoming errors in the skin biopsy pathway

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Learning objectives
After completing this learning activity, the reader should be able to recognize the need for incorporating patient safety care initiatives relating to the skin biopsy pathway and wrong-site surgery into practice; describe the national patient safety mandates that relate to the skin biopsy pathway and wrong-site surgery; and explain how to perform a simplified version of a Healthcare Failure Mode and Effect Analysis (HFMEA) to patient care as it relates to the skin biopsy pathways and wrong-site surgery.

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The skin biopsy pathway involves numerous communication requirements, technical events, human handoffs, and cognitive decisions. Every step in the process has an error rate >0. To deliver the highest quality care, dermatologists obtaining skin biopsy specimens should implement systems in their office to minimize errors. This includes the prevention of wrong-site surgery, which in most instances involves accurate communication of the correct biopsy location to the performing surgeon. Part II of this continuing medical education article presents techniques for assessing and planning improvement to the skin biopsy pathway in your office, and provides a simple online quality improvement activity that allows Board-certified dermatologists the opportunity to potentially improve aspects of the skin biopsy process in their own practices, and in the process obtain Maintenance of Certification credit. (J Am Acad Dermatol 2016;74:19-25.)

INTRODUCTION

Obtaining a skin biopsy specimen is a common procedure in dermatology, and >2.2 million skin biopsy specimens are obtained annually in dermatology offices in the United States.[1] Studies indicate that the skin biopsy pathway and wrong-site surgery are common sources of error in dermatology practice, with potential patient care and legal ramifications.[2] Accurate communication of the correct biopsy location to the performing surgeon aids in preventing wrong-site surgery.

From the first decision to obtain a biopsy specimen until the integration of those results into the patient's care plan, it has been estimated that there are approximately 20 handoffs.[2] In any one of these steps, errors can occur. While the error rate occurring in any one step in the process is small, the likelihood of an entirely error-free skin biopsy process may be lower than one might think, given the large total number of steps. For example, in a 20-step pathway, if each step is 95% reliable, the overall reliability of the pathway is 36%; if the

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reliability of each step increases to 99%, the overall reliability of the pathway is 82%.[2] Part II of this continuing medical education article explores where errors may occur in the skin biopsy process, how to identify them in your own practice, and how to potentially address and improve them.

When errors occur, dermatologists and care teams are provided with an opportunity to reflect on their causes. Sometimes a particular event is caused by individual negligence, but often the root of the error lies in the systems and processes that should have been in place to serve as safeguards. By improving systems of care in one's office, the likelihood of errors occurring can be decreased. A number of national organizations have highlighted the importance of this process of developing, achieving, and regularly measuring a local "culture of safety."[3-9] This focuses on identifying and addressing systems issues that lead individuals to engage in unsafe behaviors while maintaining individual accountability by establishing zero tolerance for reckless behavior.[10] In many dermatology practices, systems may not actually be in place to detect or report errors in the first place. The first and most fundamental step in quality improvement is acknowledging that errors do occur and creating a culture and system for effective reporting of them.

HEALTH CARE FAILURE MODE AND EFFECT ANALYSIS

Key points

- **"Failure mode" refers to anything that can go wrong during a single step of a multistep process**
- **Health care failure mode and effect analysis uses a local health care team to brainstorm ways in which things can and do go wrong in common procedures**
- **Hazard analysis is performed to prioritize which failure mode should be addressed first**

Analyzing the possible cause of any error is important, but for many in health care it is unfamiliar. When errors occur, dermatologists must try to avoid the blame and shame mindset—"If it wasn't my fault, it must have been your fault"—and instead explore in greater detail the steps of the process to determine where and why an error occurred. To help identify and better attribute causes of error, medicine has adopted and modified an analytic strategy from industry called failure mode and effect analysis (FMEA).

FMEA is a prospective and systematic approach to identify and understand contributing factors, causes, and effects of potential failures on a process, system, or practice.[11] It was developed by the US military[12] and has been in use since the 1960s in high-risk engineering industries, such as the aerospace industry.[11] For example, FMEA looks at the design of each piece of a jet engine, determines the impact of the failure of 1 engine subcomponent on the function of the whole engine, estimates the probability and overall severity of the failure, and then recommends design fixes to mitigate the risk of subcomponent failures that could lead to major or catastrophic engine failures.

Health care failure mode and effect analysis (HFMEA), a modified variant of FMEA, is a validated risk analysis method developed by the Veterans Administration (VA) National Center for Patient Safety in 2001. It combines features of FMEA from engineering and industry along with hazard analysis and critical control point—an assessment process developed by the US Food and Drug Administration to ensure food safety—and the VA's root cause analysis program.[13]

HFMEA is a 5-step process (Table I) that uses a multidisciplinary team to proactively evaluate a health

Table I. The 5 steps of health care failure mode and effect analysis

Step 1	Define the topic
Step 2	Assemble the team
Step 3	Graphically describe the process
Step 4	Conduct a hazard analysis
Step 5	Actions and outcome measures

Table II. Interpreting failure mode terminology in the process of obtaining a skin biopsy specimen

Terminology	Example
Failure of a process	Skin biopsy error occurs
Failure mode	Biopsy performed on the wrong location
	Inadequate specimen obtained
	Dermatologist never received pathology report
	Results never given to patient
Causes of a failure	Biopsy site not clearly marked for provider delegated to perform procedure
	Incorrect biopsy technique chosen
	Pathology report misplaced in the office
	Patient phone was busy 3 times, staff never tried to call them back
Effects of a failure	Treatment implemented for incorrect diagnosis
	Patient treated for actinic keratosis instead of invasive squamous cell carcinoma
	Patient does not receive biopsy results
	Surgery performed on wrong site

Table III. The skin biopsy pathway

Process step 1
Decision to perform a biopsy is made
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Process step 2
Reason(s) for obtaining biopsy and risks are discussed with patient; informed consent is obtained
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Process step 3
Biopsy details are determined: type and size of biopsy, no. of biopsies to obtain, body site or sites and location within lesion(s), and transport media
↓
Process step 4
Surgical space, equipment, supplies and staff are assembled, and transport media/containers and requisition forms are obtained, labeled, and completed
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Process step 5
Biopsy specimen(s) is/are obtained and placed into correctly labeled specimen container(s)
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Process step 6
Methods for documenting biopsy location(s) are performed, especially if skin cancer is suspected to prevent wrong-site surgery
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Process step 7
A dressing is applied and aftercare is explained to the patient
↓
Process step 8
Details of biopsy performance are documented
↓
Process step 9
Communication/transportation pathway for biopsy specimen(s) and requisition form(s) from surgical space to dermatopathology laboratory is engaged
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Process step 10
Dermatopathology laboratory performs diagnostic techniques using specimen(s) and a pathology report is generated
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Process step 11
The pathology report is transmitted to the clinician who obtained the biopsy specimen
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Process step 12
The clinician determines a course of action/therapy for the patient based on the pathology report results
↓
Process step 13
The pathology report results and proposed course of action/therapy are communicated to the patient and any additional clinicians who will need this information. If skin cancer has been identified and another clinician will be performing the definitive surgery, the methods of biopsy site documentation are transmitted
↓
Process step 14
Treatment of disease is initiated based on the pathology report results

care process.[13] It is designed for use with health care processes that have high vulnerabilities and potential for impacting patient safety.[12] Given that HFMEA has been introduced into health care in recent years, some of the terminology may be unfamiliar. Failure of a process refers to any malfunction, error, or defect that results in a process not performing as intended or not meeting desired requirements or standards. Failure mode refers to anything that could go wrong during the completion of a step in that process.[14] Causes of a failure include all possible mechanisms or means that result in the failure mode, and the effects of a failure typically include the results to the end user or customer from the failure mode. Examples of these terms relevant to the process of obtaining a skin biopsy specimen can be found in Table II. HFMEA has been applied successfully to processes in a number of areas within medicine, including blood transfusion administration, surgical instrument sterilization, medication administration on oncology wards and intensive care units, ordering magnetic resonance imaging scans for patients, and others,[15-20] but it has not yet been applied in dermatology. In these other fields, applying HFMEA principles has led to reduced errors, the recognition of previously unidentified systems errors, and in some cases, improved mortality. Specific studies analyzing exact cost savings (beyond theoretical) or efficiency gains have not been completed, to our knowledge. In the remainder of this article, we will use key concepts from the HFMEA process to describe an approach to completing a quality improvement activity relating to the skin biopsy pathway.

APPLYING QUALITY IMPROVEMENT PRINCIPLES TO THE SKIN BIOPSY PATHWAY

Key points

- **All steps in the local skin biopsy pathway should be defined and understood before deciding on how to improve the pathway**

Table IV. Subprocesses in the skin biopsy pathway process (step 6)

Process step 6	Subprocesses
Methods for documenting biopsy location(s) are performed, especially if skin cancer is suspected to prevent wrong-site surgery	Decision is made to document location Type of documentation is chosen Documentation method is performed Result is labeled Result is stored and/or transmitted to future surgeon

- **Resources are limited, so it is important to prioritize which steps would be most important to improve**
- **Interval remeasurement is important to determine progress during a quality improvement activity**

Step 1: Define the topic

The topic of an HFMEA assessment should be a health care process that is vulnerable to error and has the potential for impacting patient safety.[12] This article will address the skin biopsy pathway.

Step 2: Assemble the team

To maximize success, the quality improvement (QI) process should be performed locally, such as in a private office, dermatology practice, department, or institution. If using classic HFMEA methods, the team would ideally include 6 to 8 multidisciplinary members who are involved in the process being analyzed and include at least a few who are considered subject matter experts.[12] For dermatology practices, assembling such a large team is often not practical, and team composition would necessarily vary. A smaller number of individuals involved in the skin biopsy pathway, such as the dermatologist and medical assistant staff, could comprise an appropriate team for office-based QI. When participating for Maintenance of Certification (MOC) credit, the dermatologist is the only required participant. Other team members may bring perspectives unknown to the dermatologist, so forming even a small team to review these perspectives is encouraged. Consideration could even be given to including the patient's perspective into the quality improvement process, especially when the process to be improved involves the patient's experience of care. This has been done in other HFMEA processes in other fields.[17]

Step 3: Review and describe the process

The entire process to be analyzed should first be described in a flow diagram. This is usually performed in a "brainstorming" fashion. As a group, the team slowly clarifies all the steps involved in the process from start to finish. An example of a flow diagram for the main process steps in the skin biopsy pathway created by the authors is found in Table III. Next, subprocesses within each main process step are identified in a similar manner. For example, subprocess steps contained within skin biopsy pathway process number 6 are presented in Table IV.

Step 4: Prioritize which aspect of the pathway to improve

Once the process has been defined, the dermatologist must determine where the failure modes occur. Often, when assessing a particular multistep process, the team may determine that there are several steps with identified areas in need of improvement. One of the biggest mistakes made when first beginning to define a QI project is being too broad in the QI project objectives and trying to fix a large, complex process with a single project. Multiple small targeted QI interventions are more likely to be most successful at gradually fixing the whole process. Time and money are not limitless, so the next step in the quality improvement process is to focus the improvement effort and prioritize which step(s) to expend resources to improve. In many cases, a dermatologist can reflect and identify the specific step in the biopsy pathway where most errors occur in his or her office.

To help prioritize in the larger setting of a department or hospital, a full hazard analysis can be completed. The goal of a traditional HFMEA hazard analysis is to identify the most important components in a complex process on which to focus and improve. There are several sequential steps.[12,13,21] First, the team lists all possible failure modes. Each potential failure mode is then assessed in terms of its severity (What is the impact on patient care if it occurs?), frequency (How frequently does it occur?), and detectability (How likely would the occurrence of this failure mode be obvious enough that it would be detected before an adverse event occurs?). A quantitative hazard score is generated by multiplying the severity, frequency, and detectability scores together. The failure mode with the highest

Table V. Interventions to reduce skin biopsy process errors

Process step	Intervention to reduce error
Decision to perform the biopsy is made	Stay up to date with medical literature or educational meetings regarding skin condition biopsy indications
Informed consent is obtained	Implement procedure checklist to include informed consent
	Log or confirm decision-maker name and number as standard hard stop in electronic medical record
	Use ''teach back'' technique
	Complete periodic simulation self-assessment to practice properly detailing informed consent
Biopsy details are determined	Review part I of this continuing medical education article
	Use decision support tools (VisualDX, UpToDate, textbooks, etc)
Transport media/containers and requisition forms are obtained, labeled, and completed	Read-back label
	Perform time out that includes procedure and transport media selection
	Confirm that label/requisition form details match
	Encourage open communication with dermatopathologists for quality assurance to develop systems-based solutions when problems arise
Surgical space, equipment, supplies, and staff are assembled, biopsy is performed	Review part I of this continuing medical education article
	Use decision support tools (VisualDX, UpToDate, textbooks, etc)
	Complete hands on technical training or periodic simulated self-assessment
Methods for documenting biopsy location(s) are performed	Mark biopsy site with skin marking pen
	Photograph biopsy site that includes regional information or body landmarks
	Location read-back to match documentation and photograph
	Double check photo/patient match when uploading photograph(s) to the electronic health record
Details of biopsy performance are documented	Document biopsy location while still in the room
	Implement procedure checklist that includes procedure note check
Communication/transportation pathway for biopsy specimen(s) and requisition form(s) from surgical space to dermatopathology laboratory is engaged	Perform time out to ensure label/requisition details match before transport and immediately upon arrival in dermatopathology laboratory
Dermatopathology laboratory performs diagnostic techniques using specimen(s) and a pathology report is generated	Use barcoded specimens
	Implement 1 specimen at a time throughput rather than batch
	Laboratory performs time out during processing to confirm label match
The pathology report is transmitted to the clinician who obtained the biopsy specimen	Automated process to release report to clinician upon sign-off by dermatopathologist
	Dermatopathology time out to confirm correct referring clinician
	Automated reminder systems for clinician result management
	Automated process to release report to clinician upon sign-off by dermatopathologist
The clinician determines a course of action/therapy for the patient based on the pathology report results	Structured time allotment for patient-related activities like results management
	Continuing medical education in clinicopathologic correlation and disease management
Results and proposed course of action/therapy are communicated	Electronic results disposal, including automatic prompt or identification of context patient or context primary care providers when disposing results
	Structured time allotment for patient-related activities like results management
Treatment of disease is initiated based on the pathology report results	Ensure the health literacy of communication to patients
	Practice ''teach back'' with patients
	Process to communicate delegated plans to staff

hazard score has the greatest potential impact on patient care.

Step 5: Define actions and outcome measures

In a full HFMEA analysis—again, typically performed in the larger setting of a department or hospital—once a cause within a subprocess is deemed worthy of pursuing, an appropriate course of action is proposed, a single individual responsible for implementing or overseeing that course of action is identified, and outcome measures to verify its progress or completion are selected. This might include additional equipment or resources to obtain, new clinical steps to enact, or old clinical steps to change or discontinue. This may also involve identifying the key stakeholders that currently are involved and the key stakeholders that need to be but are not yet involved. Once the change is implemented, all the changes should be described in the written office protocols to best sustain the improvement efforts. Table V shows possible actions to take to reduce errors in the various steps of the skin biopsy pathway.

Step 6: Remeasurement and reflection

Once the action and outcomes measures are determined, the project enters its intervention stage. The duration of time in the intervention stage will necessarily vary by project, but should be designed in as short intervals as possible to allow an adequate sample size of events for remeasurement. Typically, ≥2 remeasurements are performed after the intervention stage to determine initial and sustained progress with the changes sought for improvement. After each remeasurement and at the conclusion of the project, the dermatologist and team should purposefully reflect on the data and draw conclusions. Occasionally, an initial intervention plan is determined to be flawed, and modifications to the plan may be made during the intervention stage. Barriers to success should also be identified. It is important to note that failures to improve can be just as instructive as improvements. The process of trying to improve has recognized value. There is no stipulation by the American Board of Dermatology (ABD) that quantitative improvement must be realized to earn MOC credit for QI activity.

IMPROVING THE SKIN BIOPSY PATHWAY TO EARN MAINTENANCE OF CERTIFICATION COMPONENT 4 CREDIT

Key points

- **American Board of Dermatology diplomates can earn Maintenance of Certification credit by attempting to improve the skin biopsy pathway**
- **A free, simple, focused set of online modules, designed for 1 person to complete in a relatively short period of time, has been created to assist the diplomate in assessing and improving the skin biopsy pathway in his or her office**
- **Assessment and an effort to improve the process fulfills the requirement**

For dermatologists who wish to assess potential practice gaps in their practice related to ≥1 of the steps in the skin biopsy pathway, this online module may be of value. In addition, it provides MOC credit as a practice improvement activity.[22,23] To view and participate, visit https://secure.dataharborsolutions.com/ABDermOrg/.

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Answers to CME examination

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