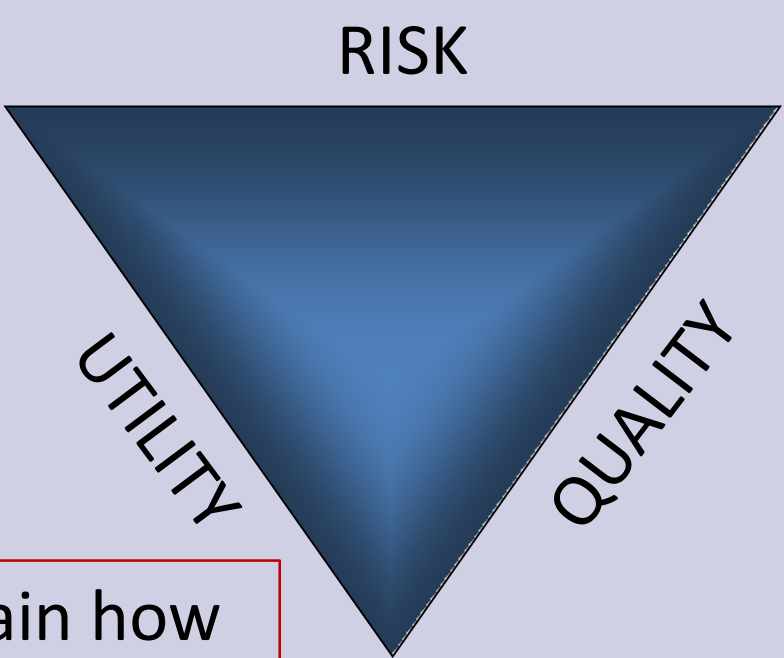


REDUCING DIAGNOSTIC ERROR

Through an Intraoperative Protocol for Microscopic Examination of Small Biopsies

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1. Describe how advancements in diagnostic screening procedures require ever more specialized handling in real time 2. Recognize how these advancements increase the risk for operative morbidity, delay in diagnosis, and diagnostic error 3. Explain how an intraoperative protocol directing interventional procedures can prevent or mitigate these problems

SITUATION

Rapid advancements in diagnostic screening methods combined with more effective therapeutic modalities have placed increasing pressure on clinicians to diagnose significant disease as early as possible. This has led to the growing use of minimally invasive interventional procedures on very early lesions to minimize morbidity. This has resulted in ever increasing numbers of specimens of ever decreasing size that harbor poorly representative and/or early borderline lesions.

This has lead to:

- ➔ Diagnostic inaccuracy and indeterminacy
- ➔ Paradoxical delay of diagnosis and so treatment
- ➔ Repeat procedures increasing risk for procedure related morbidity/mortality

PROBLEM

How can we address the problems posed by earlier, smaller, and potentially non-representative specimens so as to:

RISK: Maximize the patient's safety from repeat procedures, delay of treatment, and inappropriate therapy.

QUALITY: Minimize inconvenience, pain and suffering through multiple procedures magnified by missed or wrong diagnoses.

UTILITY: Maximize the yield of diagnosable samples on first procedure thereby reducing the additional cost of follow on procedures and their associated costs of increased morbidity.

SOLUTION

Intraoperative microscopic review of Fine Needle Aspiration [FNA] smears and Needle Core Biopsy [NCB] touch preps provides a means of reducing sampling error while increasing yield to fully characterize lesions with just one procedure. This is achieved through the establishment of close cooperation between interventional physician, pathologist, and support personnel through implementation of a set of guidelines that direct these procedures to:

- ➔ Minimize the degree of intervention as measured in passes and repeat procedures.
- ➔ Maximize the volume of diagnosable tissue to assure accuracy.
- ➔ Assure appropriate handling, preservation, and processing of specimens.
- ➔ Assure correct battery of specialized testing is carried out.

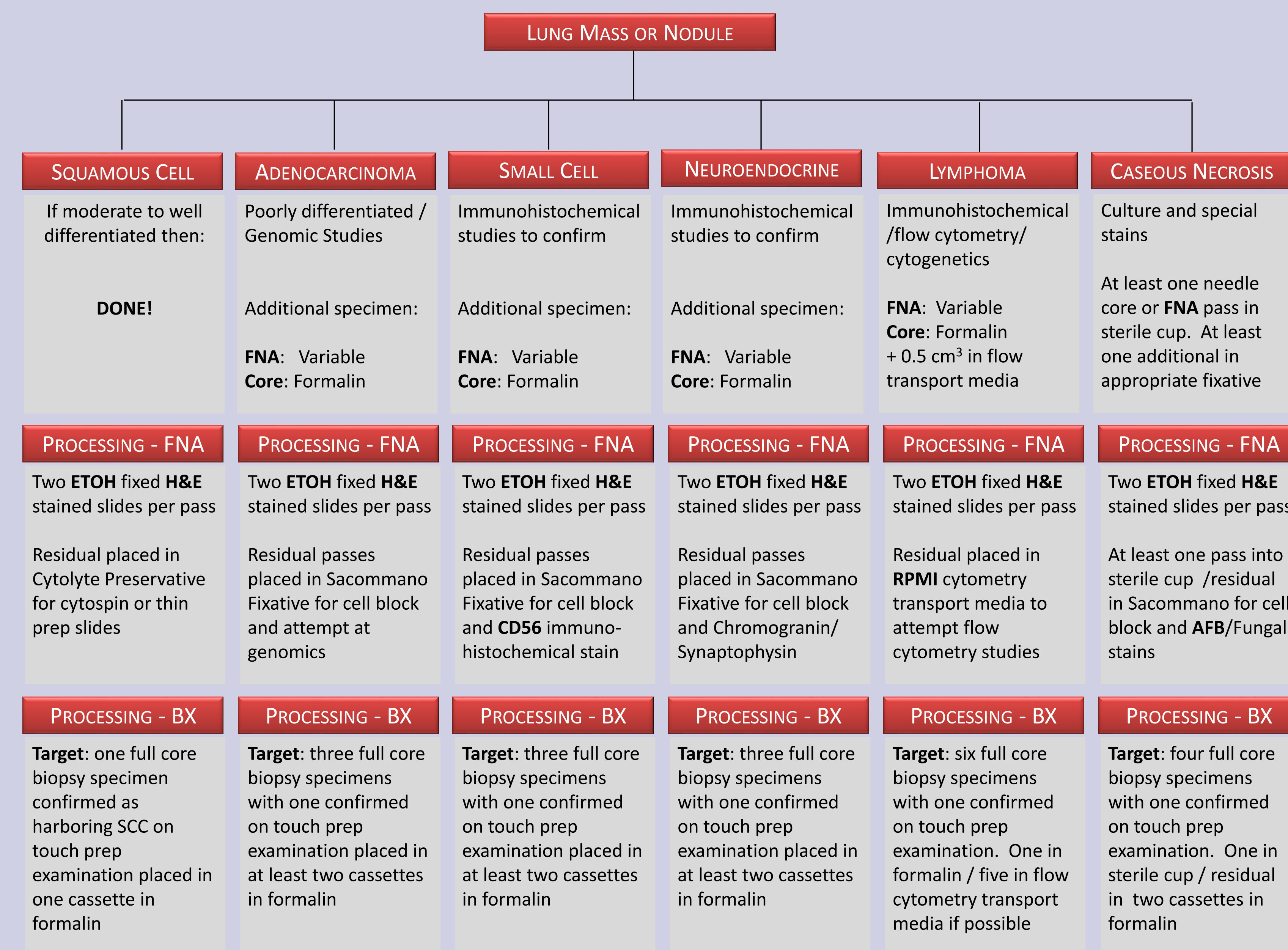
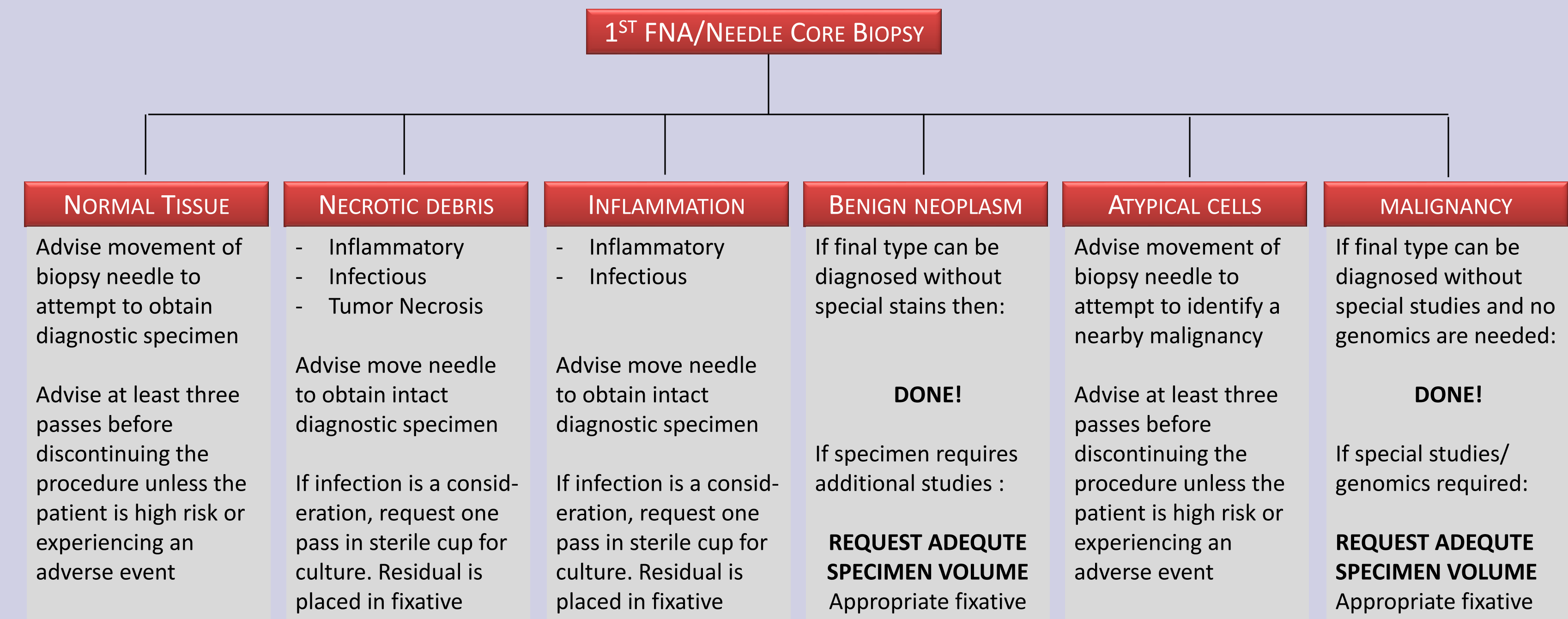
IMPLEMENTATION

I have developed a detailed protocol that includes rapid intraoperative microscopic review of initial fine needle aspirations and/or core biopsies by the pathologist. This protocol categorizes each specimen without necessarily requiring a specific diagnosis be made intraoperatively.

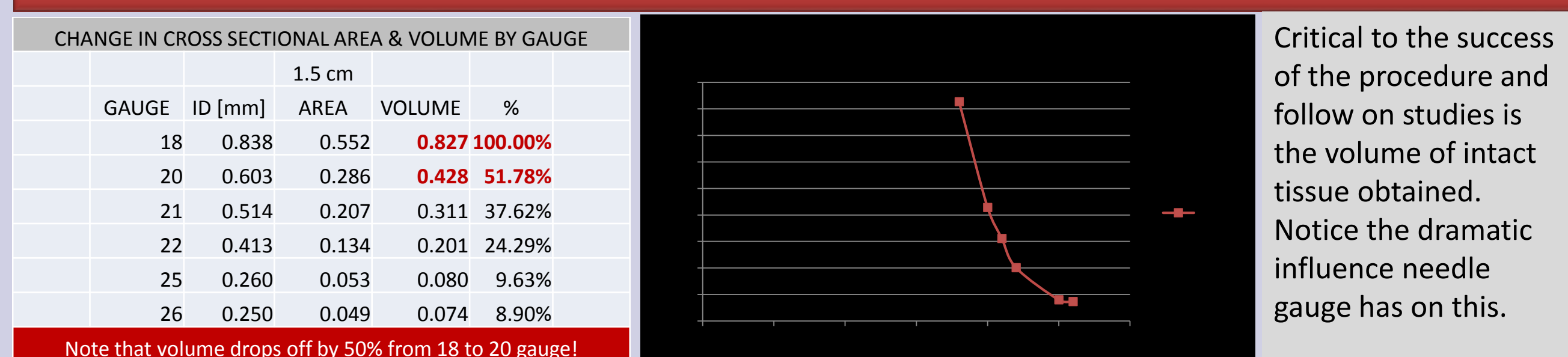
This categorization directs additional actions to be taken by the interventionist in acquiring a diagnosable specimen and the pathologist in properly preserving the specimen to assure successful follow on testing.

The goals are to minimize risk for morbidity and mortality from both the procedure and the diagnostic effort while maximizing the yield in specimen volume, quality, and diagnostic usefulness.

OVERVIEW OF PROTOCOL WITH LUNG NODULE EXAMPLE



KEY TO SUCCESS: NEEDLE GAUGE AND DIAGNOSTIC YIELD ARE EXPONENTIALLY RELATED



WE HAVE FOUND THAT 18 GAUGE IS OPTIMAL FOR BOTH FNA AND NCB. 20 – 22 GAUGE ARE ADEQUATE

REFERENCES – SELECTED:
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COST BENEFIT ANALYSIS

Application of the protocol has resulted in:

DIRECT PATIENT EFFECT:

- ➔ Reducing number of aspirations/biopsies per procedure.
- ➔ Reducing second procedures and associated costs.
- ➔ Reducing morbidity: pneumothorax, collapsed lung, hemorrhage, and hematomas

DIRECT SPECIMEN EFFECT:

- ➔ Increasing quantity and quality of specimen produced.
- ➔ Increasing quality of touch preps to assure appropriate direction of procedure.
- ➔ Facilitating tumor characterization and staging to direct appropriate therapy.

EXAMPLE

Interventional procedures to diagnose very small lung nodules that have grown slowly generally produce scant tissue upon which to make a diagnosis leading to follow up scans and additional interventions.

To the left is an abbreviated schema illustrating the key decision points for either a Fine Needle Aspiration [FNA] or a Needle Core Biopsy [NCB] of the lung nodule/mass. This is also used for mediastinal masses.

The key is to properly prepare and examine the first pass within five to ten minutes. This allows for the timely determination of:

- ➔ Needle placement for the next specimen if additional material is needed
- ➔ Condition of the lesion which may require adjusting placement as well
- ➔ Inflammatory vs benign neoplasm vs malignancy to determine follow on passes
- ➔ What additional studies may be needed to direct total number of passes
- ➔ What type(s) of preservation will be carried out to do appropriate studies
- ➔ How specimen will be split if more than one form of preservation is required

The key to properly handling follow on passes is to determine:

- ➔ If additional specimens appear representative
- ➔ If additional specimens are adequate in condition
- ➔ When an adequate volume of diagnosable specimen has been obtained
- ➔ When attempting to obtain adequate volume will compromise patient safety

To do this the pathologist wears 2.5 – 3.5x magnifier lens to examine the specimen or, when necessary uses a dissecting microscope to examine intact needle core biopsies before making touch preps or allocating the specimen to one or more preservatives.

CONCLUSION

The presence of an experienced pathologist during interventional procedures utilizing a mutually agreed upon decision tree provides significant advantages. These include but are not limited to relieving the interventionist from having to do two separate tasks; real time guidance for adjustment of the biopsy or aspiration needle position; intraoperative diagnosis allowing early termination of the procedure, and indicating when additional specimen is need as well as which preservative to utilize.

Following an intraoperative protocol increases the number of definitive diagnoses, subclassifications, and stagings in a timely manner while reducing adverse outcomes secondary to the procedure itself by eliminating the need for a second procedure.

This **Reduces Diagnostic Error** in an affordable manner that increases quality of care.