Quality Improvement Tookit

Society of Interventional Radiology

Percutaneous Image-guided Biopsy Toolkit

Introduction:

One of the basic tenets of personalized treatment algorithms, particularly in the cancer realm, is tissue procurement. While this step has provided benefit in terms of diagnosis and management for both benign and malignant diseases for years, the variation in treatment options based on molecular markers continues to expand and emphasize its importance. With percutaneous techniques being the primary avenue for most biopsies, the expertise of interventional radiologists allows us to be at the forefront for obtaining tissue in most situations.

Because of the increasing importance of biopsies, and at times the need for more tissue, biopsy adequacy is becoming more important to not only Interventional Radiologists but health care systems at large. This is reflected in the fact that biopsy adequacy is often used to not only refer to an accurate pathologic diagnosis but also may refer to patient and referring physician satisfaction in regards to the process of scheduling, timing, performance and results reporting.

There are many steps in the process from physician consultation for biopsy, correctly identifying appropriate molecular markers to test, scheduling in a timely manner, and results reporting that can lead to suboptimal outcomes. These steps involve many parts of several departments leading to complex coordination and communication which often significantly affects overall outcomes.

Being able to evaluate and prove quality is important for patient care as well as critical to fulfill reporting standards for inclusion in Merit-based Incentive Payment Systems (MIPS) Clinical Quality Measures (CQM) and/or Qualified Clinical Data Registry (QCDR) Measures. Quality improvement (QI) processes can be applied to many aspects of this service line to ensure that institutionally the program functions at the highest standards. Further, with the upcoming introduction of the VIRTEX institutional results can be compared real time to national benchmarks.

To guide individual practices to successfully perform QI projects, meet hospital and national metrics, improve patient outcomes and experiences as well as patient, and referring provider satisfaction, this toolkit attempts to highlight the basics of trying to create such a project regarding biopsy adequacy.

Therefore, we provide the following:

1. Brief review of applicable terminology
2. Published adequacy benchmarks
3. Sample quality improvement projects
4. PDSA (Plan-Do-Study-Act) cycle
5. Fishbone diagram

Clinical Scenario:

A hospital has decided to invest heavily in a new cancer clinic. As part of this clinic they are offering cutting edge therapies and diagnostic tests. A few months after "opening" the center, there have been several complaints that biopsies are not meeting standards. Oncologists and pulmonologists feel that biopsies are not being scheduled in a timely manner and, at times, are postponed. Furthermore, they do not report all molecular markers needed to make treatment decisions. You have volunteered to perform a QI project to help evaluate and potentially improve this process. You start by creating a Fishbone diagram, which after discussion allows you to pinpoint lung biopsies as the most important area to investigate. This leads you to create the following PDSA cycle to address concerns with lung biopsies.

Reference:

1. Sheth RA, Baerlocher MO, Connolly BL, Dariushnia SR, Shyn PB, Vatsky S, Tam AL, Gupta S. Society of Interventional Radiology Quality Improvement Standards on Percutaneous Needle Biopsy in Adult and Pediatric Patients. J Vasc Interv Radiol. 2020 Nov;31(11):1840-1848. doi: 10.1016/j.jvir.2020.07.012. Epub 2020 Oct 1. PMID: 33011015.

1: Brief review of applicable terminology

- **Adequate sample:** Sample is deemed sufficient for diagnosis by pathologist or cytologist.
- **Technical success:** Imaging documentation that the biopsy target was successfully sampled.
- **Clinical success:** Review of biopsy report confirms a specific histologic diagnosis, which is concordant with imaging and clinical situation as well as sufficient tissue to complete all necessary tests.
- **Benchmark:** Measurable reference point, which is based on national guidelines or institutionally established baselines (i.e. biopsy adequacy, complication rate, time to scheduling from initiation of request).

2: Published adequacy benchmarks

Benchmarking data:

QI should be based on the achievement of nationally or institutionally established baselines.

Benchmarking:

As will come to light during your quality improvement (QI) project a number of factors may influence the percentage of biopsies which are adequate for diagnosis at your practice. It is helpful to know prior to starting, and during, the process of QI what expected or "benchmarks" have been established in the literature. The Society of Interventional Radiology has launched VIRTEX, a registry to capture clinical data to provide high level benchmarks. However, until this data manifests, previously published outcomes can be utilized. A brief review of available literature for published biopsy adequacy rates can be found below.

In a retrospective review of core needle biopsies of liver lesions, Fotiadis et al, found an overall diagnostic yield of 92.6% (863/932) (1). In a national audit of the United Kingdom, which surveyed 210 departments, Howlett et al found that biopsies were adequate in 92.9% (1080/1162) in lesional biopsies and 98.3% (2118/2155) in non-lesional liver biopsies (2). This led the group to suggest an audit standard of >90%. Additional papers reporting on adequacy of liver biopsies can be found here (3-7). When evaluating native kidney biopsies Mai et al, found an adequacy rate of 93.4% (875/936)(8). Volpe et al, in a review, found that all recent series reporting on core needle biopsy of lesions showed an adequacy of >90%, while the adequacy of fine needle aspirations (FNA) ranged from 76%-97% (9). Additional papers reporting on the adequacy of renal biopsies can be found here (10-12), or in the review by Volpe et al (9). In a retrospective study, Geraghty et al, found a diagnostic accuracy of 94% (632/676) in lung lesions (13). However, in a retrospective review of 8 institutions Lee et al found that nondiagnostic results were found in 27.6% (2590/9384) procedures (14). Other references for lung biopsy adequacy can be found here (15-17).

References:

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3: Sample quality improvement projects

Potential QI project interventions, which can lead to measurable improvements in biopsy adequacy are listed below:

- Standardize minimum number of passes made

  Examples:

  - Thyroid: minimum of 2 and maximum of 3 passes if ROSE not available[1]
  - Molecular testing: 2-5 passes to ensure adequacy[2]

- Standardize combination of core needle biopsy and fine needle aspiration (FNA) for each biopsy site

  Examples:

  - Lung biopsy: combined FNA and core biopsy can increase accuracy[3]
  - Renal biopsy: core only[4,5]

- Utilize rapid onsite evaluation (ROSE) for biopsy of certain target organs:

  Examples:

  - Thyroid lesion FNA[5]
  - Renal lesions[6]
  - Liver lesions[7]
  - ROSE with telecytology[8,9] can be considered if cytology not available on site

- Standardize core biopsy needle gauge in various organ sites:

  Example:

  - Liver – 18 gauge[10]
  - Lung – 20 gauge[11,12]

- Report addendums once pathology reports are availability to allow for assessment of result concordance

References

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4: PDSA (Plan-Do-Study-Act) cycle

PDSA Worksheet

(A tool for documenting a test of change. One PDSA worksheet for each change you test. Each change may go through several PDSA cycles as you continue to learn the results)

Objective:

Reduce the number of cancellation of biopsies on the day of procedure to 0% by review of every biopsy consult by Interventional Radiologist before the patient is scheduled for the procedure.

PLAN THE TEST, INCLUDING A PLAN FOR COLLECTING DATA.

Questions and predictions:

At present, 5% of scheduled biopsies are cancelled on the day of the procedure. By implementing a process change between the 'receipt of a biopsy consult' to the 'scheduling of biopsy procedure', will lead to a 0% cancellation goal.

Who, what, where, when:

- The IR scheduling coordinator will maintain a biopsy request/review registry on excel file
- The IR scheduling coordinator will compile the order details and contact information for ordering provider and provide it to the IR in real-time. A Biopsy review box will be placed at the IR workstation.
- IR will review all requests in the box and annotate 'ok to schedule' as deemed appropriate. If more clinical information or imaging is needed, IR will contact the ordering provider for the same.
- The IR scheduling coordinator will schedule 3-pick-ups at 9am, 12pm and 3pm and schedule the biopsies deemed 'ok to schedule'
- IR scheduling coordinator will schedule the biopsy

Plan for collecting data:

IRB approval will be obtained.

Biopsy registry excel will document:

- All orders/consults placed – with time and date.
- Time and date the review was completed by IR
- Time and date the biopsy was scheduled
- Time and date the biopsy was completed
- The registry will be managed by IR scheduling coordinator and nurse coordinator.

RUN THE TEST ON A SMALL SCALE.

Describe what happened:

Preliminary Data was collected and maintained as described above.

- 50 patients were reviewed retrospectively.
- Time from consult request to scheduling the procedure was 2 days
- 48/50 patients underwent biopsy. 2 patient procedures were cancelled.
- On further evaluation, for one patient the imaging review was skipped by the IR before approval as it was not uploaded from the outside facility and the second patient was scheduled mistakenly without IR approval.
- Time from consult request to scheduling the procedure was 6 days

ANALYZE THE RESULTS AND COMPARE THEM TO YOUR PREDICTIONS.

98% IR scheduling coordinator compliance with process change for getting approval

98% IR compliance with appropriate review prior to approval

1-day delay in scheduling the procedure compared to before, however no difference in from consult request to date of procedure.

BASED ON WHAT YOU LEARNED FROM THE TEST, PLAN FOR YOUR NEXT STEP.

Determine what modifications you should make — adapt, adopt, or abandon:

- Encourage timely IR review and approval of procedure
- Encourage updating the registry in real time by the IR scheduling coordinator to not schedule an procedures without IR approval
- Encourage referring physicians to assure any OSH imaging be uploaded in PACS before placing the order. The EMR order set can be modified for this change
- Repeat PDSA for 200 patients

5: Fishbone Diagram