THYROID NODULE GUIDELINES

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Professor of Medicine
Director, Endocrinology Diabetes and Metabolism Fellowship
Mayo Clinic Florida
DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIP(S) WITH INDUSTRY

• Nothing to disclose

REFERENCES TO OFF-LABEL USAGE(S) OF PHARMACEUTICALS OR INSTRUMENTS

• Nothing to disclose
LEARNING OBJECTIVES

• Understand risk stratification of thyroid nodules
• Become familiar with available guidelines
• Appreciate updated Bethesda cytology reporting terminology (TBSRTC)
• Comprehend recommended algorithm for thyroid nodule management
Guidelines

• The Bethesda System for Reporting Thyroid Cytopathology
  • TBSRTC

• American Thyroid Association Thyroid Nodule Guidelines (2015)
  • ATA Risk Stratification System (ATA RSS)

• American College of Radiology
  • TI-RADS [Thyroid Imaging Reporting & Data System (TI-RADS™)]

• American Association of Clinical Endocrinologists (AACE) &
  AME - Associazone Medici Endocrinologi

• European Thyroid Association (ETA)

• Korean Thyroid Association (KTA)
# Cytology Thyroid FNA Classification

National Cancer Institute Thyroid Fine-Needle Thyroid FNA Classification Scheme

<table>
<thead>
<tr>
<th>Bethesda Category</th>
<th>Suggested Category</th>
<th>Alternate Category*</th>
<th>Risk of Malignancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Non-diagnostic</td>
<td>Unsatisfactory</td>
<td>?</td>
</tr>
<tr>
<td>II</td>
<td>Benign</td>
<td></td>
<td>&lt;1%</td>
</tr>
<tr>
<td>III</td>
<td>Atypia of Undetermined Significance/ Follicular Lesion of Undetermined Significance</td>
<td>Indeterminate follicular lesions, R/O neoplasm, atypical follicular lesion, cellular follicular lesion</td>
<td>5-10%</td>
</tr>
<tr>
<td>IV</td>
<td>Neoplasm</td>
<td>Suspicious for neoplasm</td>
<td>20-30%</td>
</tr>
<tr>
<td>V</td>
<td>Suspicious for Malignancy</td>
<td>n/a</td>
<td>50-75%</td>
</tr>
<tr>
<td>VI</td>
<td>Malignant</td>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>
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</tbody>
</table>
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<table>
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<tr>
<th>Bethesda Category</th>
<th>Suggested Category</th>
<th>Risk of Malignancy Ave% (range)</th>
<th>Risk of Malignancy minus NIFT-P Ave% (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Non-diagnostic</td>
<td>13 (5-20)</td>
<td>12</td>
</tr>
<tr>
<td>II</td>
<td>Benign</td>
<td>4 (2-7)</td>
<td>2</td>
</tr>
<tr>
<td>III</td>
<td>Atypia of Undetermined Significance</td>
<td>22 (13-30)</td>
<td>16</td>
</tr>
<tr>
<td>IV</td>
<td>Follicular Neoplasm (follicular neoplasm with oncocytic features)</td>
<td>30 (23-34)</td>
<td>23</td>
</tr>
<tr>
<td>V</td>
<td>Suspicious for Malignancy</td>
<td>74 (67-83)</td>
<td>65</td>
</tr>
<tr>
<td>VI</td>
<td>Malignant</td>
<td>97 (97-100)</td>
<td>94</td>
</tr>
</tbody>
</table>

(Expected 2023)
Question 1

Which of the statements below about available thyroid nodule risk stratification systems is not true?

A. ATA RSS tends to be more sensitive
B. TI-RADS tends to be more specific
C. All systems utilize five levels of cancer risk to categorize thyroid nodules
D. ATA, AACE, TI-RADS, Korean and European Thyroid RSS recommend against FNA of highly suspicious thyroid nodules < 1 cm size
E. Many physician use more than on of the systems in practice
Answer Question 1

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C. All systems utilize five levels of cancer risk to categorize thyroid nodules
D. ATA, AACE, TI-RADS, Korean and European Thyroid RSS recommend against FNA of highly suspicious thyroid nodules < 1 cm size
E. Many physician use more than one of the systems in practice
ATA Thyroid Nodule Risk Stratification

- **High Suspicion (70-90%)**
  - Hypoechoic, irregular margins
  - Hypoechoic, irregular shape
  - Hypoechoic, irregular shape, extrathyroidal extension
  - Hypoechoic, irregular shape, extrathyroidal extension with soft tissue extension
  - Nodule with regular margins, suspicious left lateral lymph node

- **Intermediate Suspicion (10-20%)**
  - Hypoechoic, solid, regular margin
  - Hypoechoic, solid, regular margin

- **Low Suspicion (5-10%)**
  - Hypoechoic, solid, regular margin
  - Partially cystic with eccentric solid area
  - Partially cystic with eccentric solid area

- **Very Low Suspicion (<3%)**
  - Spontaneous
  - Partially cystic, no suspicious features
  - Partially cystic, no suspicious features

- **Benign (<1%)**
  - Cyst

Risk of malignancy
# ACR TI-RADs

<table>
<thead>
<tr>
<th>Composition (Choose 1)</th>
<th>Feature Points</th>
<th>Echogenicity (Choose 1)</th>
<th>Feature Points</th>
<th>Shape (Choose 1)</th>
<th>Feature Points</th>
<th>Margin (Choose 1)</th>
<th>Feature Points</th>
<th>Echogenic Foci (Choose All That Apply)</th>
<th>Feature Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feature</td>
<td>Points</td>
<td>Feature</td>
<td>Points</td>
<td>Feature</td>
<td>Points</td>
<td>Feature</td>
<td>Points</td>
<td>Feature</td>
<td>Points</td>
</tr>
<tr>
<td>Cystic/ Almost Completely Cystic Spongiform</td>
<td>0</td>
<td>Anechoic</td>
<td>0</td>
<td>Wider-than-tall</td>
<td>0</td>
<td>Smooth</td>
<td>0</td>
<td>None or Comet-tail artifacts</td>
<td>0</td>
</tr>
<tr>
<td>Mixed Cystic/Solid</td>
<td>1</td>
<td>Hyperechoic or Isoechoic</td>
<td>1</td>
<td>Taller-than-wide</td>
<td>1</td>
<td>Ill-defined</td>
<td>0</td>
<td>Macro-calcifications</td>
<td>0</td>
</tr>
<tr>
<td>Solid/ Almost Completely Solid</td>
<td>2</td>
<td>Hypoechoic</td>
<td>2</td>
<td>Lobulated or Irregular</td>
<td>2</td>
<td>Peripheral (rim) calcifications</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Very Hypoechoic</td>
<td>3</td>
<td>Extra-thyroidal extension</td>
<td>3</td>
<td>Punctate echogenic foci</td>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Add Points from all Categories for TI-RADS Score

- **0 Points**
  - TR1: Benign
    - No FNA
- **2 Points**
  - TR2: Not Suspicious
    - No FNA
- **3 Points**
  - TR3: Mildly Suspicious
    - FNA if ≥ 2.5 cm
    - Follow if ≥ 1.5 cm
- **4 - 6 Points**
  - TR4: Mildly Suspicious
    - FNA if ≥ 1.5 cm
    - Follow if ≥ 1 cm
- **≥ 7 Points**
  - TR5: Highly Suspicious
    - FNA if ≥ 1 cm
    - Follow if ≥ 0.5 cm

Content created by author for this presentation
## Thyroid Nodule Risk Stratification Systems

<table>
<thead>
<tr>
<th>Society</th>
<th>Benign</th>
<th>Low Risk</th>
<th>Mildly Suspicious</th>
<th>Moderately Suspicious*</th>
<th>Highly Suspicious</th>
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</thead>
<tbody>
<tr>
<td>ACR</td>
<td>TI-RADS 1</td>
<td>TI-RADS 2</td>
<td>TI-RADS 3</td>
<td>TI-RADS 4</td>
<td>TI-RADS 5</td>
</tr>
<tr>
<td></td>
<td>No FNA</td>
<td>No FNA</td>
<td>FNA ≥ 2.5 cm</td>
<td>FNA ≥ 1.5 cm</td>
<td>FNA ≥ 1.0 cm</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Follow ≥ 1.5 cm</td>
<td>Follow ≥ 1.0 cm</td>
<td>Follow ≥ 0.5 cm</td>
</tr>
<tr>
<td>ATA</td>
<td>No FNA</td>
<td>Consider FNA</td>
<td>FNA ≥ 1.5 cm</td>
<td>FNA ≥ 1.0 cm</td>
<td>FNA ≥ 1.0 cm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>≥ 2 cm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AACE/ACE/AME</td>
<td>No FNA</td>
<td>FNA ≥ 2.0 cm</td>
<td>-----(^p)</td>
<td>FNA ≥ 2.0 cm</td>
<td>FNA ≥ 1.0 cm</td>
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<tr>
<td></td>
<td></td>
<td>+ other risk(^c)</td>
<td></td>
<td></td>
<td>Selective FNA &gt; 0.5 cm</td>
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<tr>
<td>ETA</td>
<td>EU-TIRADS 2</td>
<td>EU-TIRADS 3</td>
<td>-----(^p)</td>
<td>EU-TIRADS 4</td>
<td>EU-TIRADS 5</td>
</tr>
<tr>
<td></td>
<td>No FNA</td>
<td>FNA ≥ 2 cm</td>
<td></td>
<td>FNA ≥ 1.5 cm</td>
<td>FNA ≥ 1.0 cm</td>
</tr>
<tr>
<td>KTA</td>
<td>K-TIRADS 2</td>
<td>K-TIRADS 3</td>
<td>-----(^p)</td>
<td>K-TIRADS 4</td>
<td>K-TIRADS 5</td>
</tr>
<tr>
<td></td>
<td>FNA ≥ 2 cm</td>
<td>FNA ≥ 1.5 cm</td>
<td></td>
<td>FNA ≥ 1.0 cm</td>
<td>FNA ≥ 1.0 cm</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Selective FNA &gt; 0.5 cm</td>
</tr>
</tbody>
</table>

\(^{p}\) = Patient preference

*Adapted from Bernet VJ, Chindris AM. J Nucl Med. 2021 Jul;62(Suppl 2):13S-19S.*
Survey of Utilization: Five Thyroid RSS

Adapted from Hoang et al. Thyroid 2022;32:675
## ACR TI-RADS vs. ATA RSS

<table>
<thead>
<tr>
<th>RSS</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>NPV</th>
<th>PPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATA</td>
<td>92%</td>
<td>10%</td>
<td>79%</td>
<td>27%</td>
</tr>
<tr>
<td>ACR TI-RADS</td>
<td>74%</td>
<td>47%</td>
<td>84%</td>
<td>33%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RSS</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Positive Likelihood Ratio</th>
<th>Negative Likelihood Ratio</th>
<th>Diagnostic Odds Ratio</th>
<th>AUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACR</td>
<td>0.85</td>
<td>0.68</td>
<td>2.98</td>
<td>0.22</td>
<td>15.23</td>
<td>0.8553</td>
</tr>
<tr>
<td>Kawk</td>
<td>0.94</td>
<td>0.62</td>
<td>3.23</td>
<td>0.08</td>
<td>43.15</td>
<td>0.9101</td>
</tr>
<tr>
<td>ATA</td>
<td>0.94</td>
<td>0.44</td>
<td>2.06</td>
<td>0.16</td>
<td>13.33</td>
<td>0.8976</td>
</tr>
<tr>
<td>KTA</td>
<td>0.85</td>
<td>0.47</td>
<td>2.60</td>
<td>0.18</td>
<td>14.57</td>
<td>0.9022</td>
</tr>
<tr>
<td>ETA</td>
<td>0.85</td>
<td>0.61</td>
<td>2.84</td>
<td>0.21</td>
<td>13.18</td>
<td>0.8810</td>
</tr>
</tbody>
</table>

- ACR & ATA overall similar in classification; ATA lower FNA size cutoffs
- ATA more unnecessary biopsies: ↓ Specificity but ↑ sensitivity
- ATA RSS ~7-10% of nodules aren’t classifiable
## Non-classifiable ATA nodules

<table>
<thead>
<tr>
<th>Study</th>
<th>ATA Non-classifiable</th>
<th>Malignancy risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yoon (Korea) 2016</td>
<td>3.4%</td>
<td>18%</td>
</tr>
<tr>
<td>Rosario (Brazil) 2017</td>
<td>3.9%</td>
<td>16.7%</td>
</tr>
<tr>
<td>Middleton (USA) 2017</td>
<td>13.9%</td>
<td>10%</td>
</tr>
<tr>
<td>Ha (Korea) 2018</td>
<td>7.6%</td>
<td>10%</td>
</tr>
<tr>
<td>Pantano (Italy) 2018</td>
<td>5%</td>
<td>10%</td>
</tr>
</tbody>
</table>

The composition/echogenicity of the nodules is as follows:

- Mixed cystic/solid with SF: 44%
- Hyper/Iso solid with SF: 27%
- Composition/echogenicity unclear: 29%
Non-classifiable ATA nodules

- Mixed cystic/solid with SF: 44%
- Hyper/Iso solid with SF: 27%
- Composition/echogenicity unclear: 29%

ATA Classifiable: 90%

Yoon Radiology 2016;278:917; Rosario Endocrine 2017;56:442; Middleton AJR 2018;210:1148; Ha Thyroid 2018;28:1532; Pantano Eur J Endocrinol 2018; 178:595
Algorithmic Approach to RSS

- Covers more combinations of features since uses a group of suspicious features
- Allows for LIMITING certain combinations such as spongiform/microcystic + echogenic foci
- Maintains the ATA atlas with addition of new combinations of sonographic features
- Abnormal cervical LNS and CLEAR extrathyroidal extension are considered HIGH suspicion and removed from algorithm
CONSISTENCY

SOLID (>90% solid)

CYSTIC (>10% cystic)

Cannot assess
SOLID
(>90% solid)

Mixed echogenicity nodules: Classify by dominant echogenicity

Markedly hypoechoic (c/w strap muscle)

Hypoechoic (but not markedly hypoechoic)

Iso/Hyperechoic

Suspicious features (SF): irregular outer nodule margins (jagged/spiculated/lobulated), Tall>Wide shape, **intrasonid** punctate echogenic foci (PEF), macrocalcals, irreg or non-uniform halo
SOLID (>90% solid)

Algorithm: Consistency → Echogenicity → SF

High suspicion
- Marked hypo
- AND > 1 SF
- Hypoechoic
- AND > 2 SF

Intermediate susp
- Marked hypo NO SF
- Hypoechoic AND 1 SF
- Iso/Hyper AND > 1 SF

Low suspicion
- Hypo/Iso/Hyper
- AND NO SF

Solid nodule suspicious features (SF): irregular outer nodule margins, TTW shape, intrasolid punctate echogenic foci (PEF), macrocalcs, irreg or non-uniform halo
CYSTIC (>10% cystic)

- Partially Cystic
- Spongiform/
  Microcystic
  Interspersed cystic
  regions
- Entirely cystic

BENIGN
**Partially cystic**

**High Suspicion**
- Solid component w/ acute angled protrusion or jagged/spiculated interface with cystic interface
- AND
- INTRASOLID PEF/MACROCALCS

**Intermediate Suspicion**
- > 1 feature
- Solid component w/ acute angled protrusions or jagged/spiculated interface with cystic interface
- NO INTRASOLID PEF/MACROCALCS

**Low Suspicion**
- Solid component w/ lobulated interface with cystic or concentric (>50% nodule volume)

**Very low Suspicion**
- Nodules that lack all of the described features
Microcystic/Spongiform
Interspersed cystic regions

Macrocaltications Do Not Alter Malignancy Risk
Within the American Thyroid Association Sonographic
Pattern System When Present in Non-High
Suspicion Thyroid Nodules

Kristin Kobaly, Caroline S. Kim, Jeff E. Langer, and Susan J. Mandel

Low suspicion
If ≥1 present macrocalcification, jagged/spiculated/
lobulated outer nodule margin or an irregular halo

Very low suspicion
solid components are all spongiform/microcystic

Using Artificial Intelligence to Revise ACR TI-RADS
Risk Stratification of Thyroid Nodules: Diagnostic
Accuracy and Utility. Radiology 2019; 292:112

Benjamin Widman-Tolinse, MD • Matesz Badu, MD • Jenny K. Huang, MB, BS • William D. Middleton, MD •
David Thayer, MD • Ryan G. Short, MD • Franklin N. Tealer, MD, CM • Maciej A. Mazurewski, PhD

NOT PEFs
Consistency cannot be assessed due to dense peripheral calcifications

**High suspicion**
- Peripheral calcs with protruding soft tissue
- OR
- Central dense calcifications

**Intermediate susp**
- Irregular peripheral calcs
- NO protruding soft tissue

**Low suspicion**
- Thin regular peripheral calcifications
- NO protruding soft tissue
2016 ATA Nodule Sonographic Pattern Risk of Malignancy Rec 8

High Suspicion
- microcalcifications
- hypoechoic nodules, irregular margin

Intermediate Suspicion
- hypoechoic, solid regular margin
- hypoechoic, taller than wide

Low Suspicion
- hypoechoic solid regular margin
- partially cystic with eccentric solid area

Very low Suspicion
- spongiform
- partially cystic no suspicious features

Benign
- cyst

Any nodule with ETE or abnl LNS
Which of the statements below about management of thyroid nodules with indeterminate cytology is correct?

A. Repeat FNA in 3-6 months is not a legitimate management option in cases of AUS (Bethesda III) cytology
B. The PPV for available molecular testing assays in typically $\geq 85\%$
C. Benign molecular testing with available assays correlates with a malignancy risk of $< 1\%$
D. Routine use of molecular assays is not recommended for Bethesda V and VI nodules
E. Nodule surveillance is not a legitimate management option
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D. Routine use of molecular assays is not recommended for Bethesda V and VI nodules
E. Nodule surveillance is not a legitimate management option
Summary of Most Prevalent Molecular Testing Assays

<table>
<thead>
<tr>
<th>Method</th>
<th>Afirma® GSC</th>
<th>ThyroSeq® v3.0</th>
<th>ThyGeNEXT ® &amp; ThyraMIR®</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Next Generation Sequencing RNA</td>
<td>Next Generation Sequencing</td>
<td>Next Generation Sequencing &amp; microRNA expression</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>91.10%</td>
<td>94.00%</td>
<td>88.60%</td>
</tr>
<tr>
<td>Specificity</td>
<td>68.30%</td>
<td>82.00%</td>
<td>85.10%</td>
</tr>
<tr>
<td>NPV</td>
<td>96.10%</td>
<td>97.40%</td>
<td>99.00%*</td>
</tr>
<tr>
<td>PPV</td>
<td>47.10%</td>
<td>66%</td>
<td>75.00%*</td>
</tr>
<tr>
<td>Cancer Prevalence</td>
<td>23.70%</td>
<td>28.0%</td>
<td>32.10%</td>
</tr>
<tr>
<td>Cost (Out of Network)</td>
<td>$$$$</td>
<td>$$</td>
<td>$$$</td>
</tr>
</tbody>
</table>

$ = 0-1999; $$ = 2000-3999; $$$ = 4000-5999; $$$$ = ≥ 6000

* Binary Test Performance

Updated 1 Nov 2022
Management of indeterminate thyroid nodules with molecular testing results

**Indeterminate thyroid nodule (Bethesda III/IV)**

**Molecular testing**

**Afierna GSC**
- **Test type**: Afirma GSC
- **Test result**:
  - Benign: 4%
  - Suspicious: 50%
- **Risk of Malignancy/NIFTP**: 4%
- **Tumor Type**: Unknown
- **Management**: Observation

**ThyGeNEXT+ ThyraMIR**
- **Test type**: ThyGeNEXT+ ThyraMIR
- **Test result**:
  - Negative: 4%
  - Moderate: 30%
  - Positive: 74%
- **Tumor Type**: Unknown
- **Management**: Observation or Lobectomy

**Thyroseq v3**
- **Test type**: Thyroseq v3
- **Test result**:
  - Negative: 3%
  - Positive: RAS-like mutations or GEA: 30-80%
  - Positive: Hürthle cell-Type CNA: 40-80%
  - Positive: BRAF-like mutations or GEA: 95-100%
  - Positive: High-risk mutation: 98-100%
- **Risk of Malignancy/NIFTP**: 3%
- **Tumor Type**:
  - NIFTP or low-risk cancer
  - Intermediate-risk cancer
  - Intermediate-risk cancer
  - High-risk cancer
- **Management**:
  - Observation
  - Lobectomy
  - Lobectomy or total thyroidectomy
  - Lobectomy or total thyroidectomy
  - Total thyroidectomy +/- lymph node dissection

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*Chart assumes absence of compressive symptoms and significant contralateral disease

*At disease prevalence of 20-30%

*Gene-expression alterations

**Copy number alterations**
ATA Management Guidelines for Adult Patients with Thyroid Nodules: Preview 2022

The ATA Thyroid Nodule Guidelines Task Force

<table>
<thead>
<tr>
<th>Endocrinology</th>
<th>Endo Surgery</th>
<th>OHNS Surgery</th>
<th>Cytology</th>
<th>Radiology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trevor Angell</td>
<td>Carmen Solorzano</td>
<td>Lisa Orloff (co-chair)</td>
<td>Ed Cibas</td>
<td>Jill Langer</td>
</tr>
<tr>
<td>Vic Bernet</td>
<td>Michael Yeh</td>
<td>Maisie Shindo</td>
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<td>Cosimo Durante</td>
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<td>Ana Luisa Maia</td>
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<td>Susan Mandel (co-chair)</td>
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<td>Sarah Mayson</td>
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<td>David McFadden</td>
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<td>Jennifer Sipos</td>
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Methodology

8 writing groups with 3-4 members each

1. Intro and methods, Screening, Pre-US & FNA Evaluation
2. Ultrasound based risk stratification
3. Decision-making based on US
4. FNA cytology reporting
5. Bethesda I and II nodules
6. Bethesda III, IV, V* nodules (molecular testing)
7. Surgery/Interventions
8. Special Populations

*Bethesda VI = Thyroid Cancer Guidelines
Group 8: Special Populations

- Pregnancy
- Transplant
- Bariatric surgery
- Older patients

Other Recent ATA Guidelines:
NCCN Management of Indeterminate Nodules
AUS/FLUS

Atypia of undetermined significance/ Follicular lesion of undetermined significance (AUS/FLUS) (Bethesda III)

- High clinical and/or radiographic suspicion of malignancy
  - Yes
  - Consider lobectomy or total thyroidectomy for definitive diagnosis/treatment
  - See PAP-1
  - See FOLL-1
- No
  - Consider repeat FNA
  - Consider diagnostic lobectomy (if Bethesda III on 2 or more occasions)
  - Consider molecular diagnostics (See THYR-2)
  - Consider nodule surveillance as recommended by the ATA or TI-RADS

Thyroid Nodule Management Algorithm

QUESTIONS & DISCUSSION
THANK YOU FOR JOINING US IN THIS COURSE

Rochester, Minnesota
Phoenix, Arizona
Jacksonville, Florida