Thyroid practice Enhancements ATA- 2013.

J. Woody Sistrunk, MD
Jackson Thyroid & Endocrine Clinic, PLLC
Jackson, Mississippi
THYROIDOLOGY
PRACTICE ENHANCEMENTS

In the order of importance.
2 sections:

1. An Introduction to Outpatient Nuclear Medicine
2. An Overview of Starting a Clinical Laboratory
AN INTRODUCTION TO NUCLEAR THYROIDOLOGY IN THE OUTPATIENT PRACTICE OF ENDOCRINOLOGY

J. Woody Sistrunk, MD, FACE, ECNU
• Radiation Safety Officer
Why **Nuclear Medicine** in Endocrinology?

- **Who knows more about the thyroid than an endocrinologist?**
- **Proper safety instructions and reassurance to YOUR patients.**
- **Making sure YOUR patients are treated appropriately.**

**SAFTEY INSTRUCTIONS FROM Hospital NUCLEAR MEDICINE:**
- “In that room you will find a metal box.
- In that box you will find a lead container.
- In that container is a pill.
- Take it and leave.”

**PUBLIC PERCEPTION**
DID YOU KNOW THAT ENDOCRINOLOGISTS:

- Can have a Nuclear Medicine Hot lab in the office.
  - Thyroid Uptakes
  - Radioactive iodine therapy for hyperthyroidism.
  - Radioactive iodine therapy for thyroid cancer.
- With these procedures, you become the nuclear medicine physician/technologist.
  - Maintaining complete control of quality and decisions of your patients outcomes.
  - Ensuring correct instructions given to patients and safety measures followed.
  - Verifying all questions are answered.
NUCLEAR MEDICINE IN THE OUTPATIENT PRACTICE OF ENDOCRINOLOGY

OUTLINE

• Licensure
• AACE Course
• Equipment
History of $^{131}$I Therapy
It is OUR heritage and OUR History!!

- **1946-1970**
  - Endocrinology

- **1970-1993**
  - Nuclear Medicine

- **1993-Present**
  - ♠American Association of Clinical Endocrinologists (AACE) Initiative.
- Missed diagnosis
- Failure to discuss other treatments
- Failure to discuss non-thyroid problems
- Misadministration
- Loss to follow-up
- “Thyroid uptake is low consistent with hypothyroidism.”
- “Thyroid uptake is low, r/o paraneoplastic process.”
NUCLEAR ENDOCRINOLGY
Agreement State vs. Non-Agreement State

- **Agreement State**
  - A state that has signed an agreement with the Nuclear Regulatory Commission under which the state regulates the use of byproduct, source, and small quantities of special nuclear material in that state.

- **Non-Agreement State**
  - The state is governed by the applicable laws of the **Nuclear Regulatory Commission (NRC)**.
Agreement States

Source: www.nrc.gov
What is a Radioactive Materials (RAM) License?

- Issued to your clinic, or the hospital where you have privileges, by the NRC or Agreement State.

- Allows the facility to:
  - order
  - receive
  - possess
  - use radioactive materials.
Who is an Authorized User?

**Authorized Users** are physicians listed on the radioactive materials license who are authorized to prescribe and administer particular radiopharmaceuticals for specific diagnostic or therapeutic procedures.
What will I be able to do as an Authorized User of Radioactive iodine?

1. Thyroid Uptakes (I^{131}, I^{123})

2. Radioactive Iodine (I^{131}) treatment for Hyperthyroidism.

3. Radioactive Iodine (I^{131}) treatment for thyroid cancer / remnant ablation.

NOTE: YOU WILL NOT HAVE THE ABILITY TO PERFORM THYROID SCANS. ********
What Do I Have To Do To Become An Authorized User?

- **80 hours of classroom instruction with an emphasis on radiation safety, physics and math.**

- **AACE 80 HOUR COURSE.**

- Board certification by a medical specialty board.

- Supervised treatment of 3 patients with less than 33 mCi. (Hyperthyroidism)

- Supervised treatment of 3 patients with more than 33 mCi. (Thyroid cancer).
AACE NUCLEAR MEDICINE COURSE
Kansas City, Missouri
Fall 2013
Go to aace.com for details.
How to Get Started

**What to Know?**

- License requirements in your state.
- Equipment required.
- Layout of nuclear medicine hot lab.

**Who to contact?**

- State nuclear regulatory agency
- Physicist
- Nuclear Pharmacy
SIMPLE “HOT LAB” LAYOUT

- Essentials include a sink and a few electrical outlets.
- *This can be the same room used for ultrasound exams.*
- The same stretcher can even be used.
Nothing this Fancy, Nothing this complicated.

- No special lead-lined room.
- No special facilities needed.
- **But this is impressive!!!!!!!!!!**
Essentials include a sink and a few electrical outlets.

*This can be the same room used for nuclear medicine and ultrasound exams.*

The same stretcher can even be used.
SIMPLE PROCEDURE ROOM LAYOUT
PROCEDURE ROOM
MICROSCOPE LAYOUT
So now it’s time to set up a **HOT LAB**!

**WHAT WILL I NEED TO PURCHASE??**

- Uptake System
- Dose Calibrator
- Geiger Counter
HOW MUCH WILL ALL OF THIS COST??

- Uptake System-- $10,000-$14,000
- Dose Calibrator-- $6000-$8000
- Neck Phantom-- $275
- Geiger Counter -- $1000

**Total Hot Lab Setup**
$20,000- $24,000
HOW MUCH EXPOSURE WILL I RECEIVE??–

- **Minimal !!! If any.**
- **No liquid!!!!!, all capsules arrive as pre-ordered unit doses.**
- **VERY SAFE♠♠**
- **HOW DO YOU KNOW IF YOU ARE EXPOSED??**
- **Film Badges.**
- **WEEKLY Bioassay-** which is simply placing the uptake probe over the neck will be performed weekly to confirm that radioactive iodine is not absorbed.
YES, it will pay for itself!!!!!!!!!!!

3 UPTAKES/ MONTH= Paying for itself.

- In practice 11 years.
  - uptakes. 774
  - \(^{131}\) therapies. 865

- PERSPECTIVE-
- Jackson Thyroid & Endocrine Clinic-- 2011
  - Ultrasound only- 1093
  - US guidance with FNA 305
  - FNA- 305
  - Uptakes- 54
  - Therapies- 45

- ♠HENCE, Thyroid Ultrasound is critical first. ♠
Fellows: WHILE IN TRAINING

- Pursue all of the requirements needed for licensure.
- Review this talk with more detail at aace.com.
- Get to know the radiation safety officer at your institution (who often times is not a radiologist) and try to be put on the institution license as an “official user”.

CAUTION
RADIOACTIVE MATERIALS
While Interviewing

- Ask about the possibility of you having a “hot lab” and doing your own nuclear medicine procedures.
- Make sure you have access to a good ultrasound machine.
- Be specific with monetary figures, space requirement and the long term money-making potential.
PATHWAY TO LICENSURE
Certification, Licensure, then Accreditation.

CASES
- 3 Hyper
- 3 cancer

80 hour AACE/DTC course

STATE/ NRC RAM LICENSE

ICANL
Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories

ICANL LAB Accreditation
Getting cases:

A PROBLEM AT TIMES

- While you are still in fellowship, if you have any desire to become licensed in this, pursue the required cases (3 hyperthyroidism, 3 cancer.)
- Assist with dose decisions, safety instructions administration.
- Have a preceptor sign the appropriate NRC preceptor attestation form.
CONCLUSIONS:

- Thyroid Doctors treating Thyroid Disease.

- A thyroid practice is a reality if you are willing to pursue it.
“Yes, my goitre is gone and now I am well and happy.”
THYROIDOLOGY

PRACTICE ENHANCEMENTS

*In the order of importance.*
IN-OFFICE

POINT OF CARE LABORATORY
LAB OUTLINE

1. Licensure
2. Equipment

Never enough equipment in the practice of Thyroidology
WHO IS THIS MAN???

HINTs:

- Invented the radiation film badge
- Invented polarized lenses
- Had a role in changing our lives forever.
Edwin H. Land

- Inventor of:
  - The Polaroid Land Camera
  - Polarized lenses.
  - The radiation film badge.
- But what does he have to do with the practice of medicine?
The Polaroid Camera changed the world.

- Pictures were available immediately.
- *Good, bad, or ugly results were available immediately.*
- No one was able wait for results anymore.
- *Land was responsible for the expectation of the results in clinical medicine anticipated immediately by the patient (and Physician/Endocrinologist.)*
Laboratory Medicine is essential is the heart of endocrinology.

Without lab, we are doomed merely to watch and guess.
Why Laboratory Medicine in Thyroidology?

- “BUT I AM SO OBESE AND TIRED, IT MUST BE MY THYROID!!!!!!!!!!”
- The decisive “NO” = PRICELESS!!!!!!!!!!
CLIA CERTIFICATION

LABORATORY MEDICINE
LABORATORY MEDICINE IN THE CLINICAL PRACTICE OF ENDOCRINOLOGY

CLIA CERTIFICATION
What is an OFFICE-BASED LABORATORY?

- Office-Based Laboratory –
  - Defined as a clinical laboratory used by a fully licensed physician to test specimens collected primarily from patients of the practice.
  - It is usually located at the physicians principal sight of care.
LABORATORY DIRECTOR -

- Responsible for the overall operation of the laboratory and the competency for all laboratory personnel.
HOW DO I BECOME A LABORATORY DIRECTOR?

- Certification in anatomic or clinical pathology.
- One year of laboratory training in residency.
- There’s still time for this.

OR

- 20 hours of CME credits of training on the responsibilities of the laboratory director. – http://www.cola.org/
This is the location for the Laboratory Directors Online Course.

http://www.cola.org
LABORATORY MAKE-UP

- **LABORATORY DIRECTOR - YOU**
  - Responsible for the overall operation of the laboratory and the competency for all laboratory personnel.
  - The first step of getting this designation is to finish the on-line portion of the laboratory course.

- **TECHNICAL CONSULTANT - YOU**
  - Responsible for technical and scientific oversight of the laboratory.

- **CLINICAL CONSULTANT - YOU**
  - The physician that orders the appropriate tests.

- **TESTING PERSONEL - Hopefully someone else.**
  - GED/High School diploma and documented training appropriate to the test being performed.
  - www.cola.org
THYROIDOLOGY WITHOUT LAB IS LIKE FISHING WITHOUT WORMS.

- LAB is critical
- **But the TSH/Free T4 is the essential part of the enterprise.**
- From vein to results on paper in 20 minutes.
- Face to face decision making.
  - Are you taking your medicine.
  - I will write your 90 day RX now.
  - A note to PCP, recommending planned follow-up.
A VAST MENU OF TESTS ARE AVAILABLE FOR THE OFFICE-BASED LAB

- TSH/ Free T4
- Simple Chemistry
- CBC
- COMPLEX LABS:
  - TSH/FT4
  - HgbA1c
  - MANY OTHERS.
- Clia-Waved Tests.

**NOTE: CLIA NOT REQUIRED FOR FNA ADEQUACY!!!!!!!!!!!
LABORATORY IMPROVES CLINICAL OUTCOMES

- 1. FASTER DIAGNOSIS AND TREATMENT.
- 2. IMPROVED PATIENT COMPLIANCE.
- 3. LABORATORY CAN MODEL THE NATURE OF YOUR PRACTICE.

“TSH and FREE T4 in < 30 minutes”
“You’re ONE-STOP THYROID SHOP”
What are the advantages of having an in office laboratory??

- **CLINICAL RESEARCH**
  - Phase 3 and Phase 4 drug studies are quickly becoming a big part of the private practice of Endocrinology.
  - Having a laboratory makes your office a valuable site for data collection in these studies.
  - Sites with laboratories are considered “more desirable.”
  - **MAKE YOUR LAB WORK FOR YOU!!!!!!!**
DISADVANTAGES OF AN OFFICE LABORATORY.

- Costs.
- Regulations.
- Personnel.
  - Technologist
  - Phlebotomist
  - Laboratory Director (MD)
My Current Practice
With POINT OF CARE LAB

- Lab Drawn
- Patient Seen
- Lab Available
- LAB IMPORTED INTO EMR
- EMR Note sent to referring physicians.
- RX written/wired.
- Disposition MADE!
- Follow-up scheduled.

- All inside of 30 minutes.
RESULTS TO PATIENTS

- Patients want results.
- Face to face results cut down on questions and confusion.
- If you see 25 patients a day, you either have to pay the salary of the lab tech who processes the labs or another nurse that will spend tomorrow tracking down the patient, verifying results, calling the pharmacy, and re-arranging follow-up.
- In the end, make it a time-saving, money making proposition.
- **Set the standard!!!!!!!!!!**
To Recap—

The Advantages of Having an in office laboratory.

- PATIENT SATISFACTION
- CONVENIENCE
- Changes to treatment regimen can be made **FACE TO FACE**.
- Patient understanding is clearly better when communicated directly by the physician.
- **FEWER PHONE CALLS** or MAILING prescriptions.
- **FASTER DIAGNOSIS AND TREATMENT**.
- **LESS ANXIETY** WAITING FOR RESULTS.
- Ability to send Obese and Tired to an Internist!
RECAP– Many Reasons to have a lab in the office.

- **It’s good for the patient.**
  - Convenient, faster diagnosis and treatment.

- **It’s good for the practice.**
  - Improved efficiency, Patient Satisfaction.

- **It’s good for revenue.**
  - It keeps the bills paid.

- **It’s good for the physician.**
  - YOU ARE IN CONTROL!!!!!!!!!!!!!!!!
  - IT MAKES YOU A VALUABLE COMMODITY.
**HOW PROFITABLE IS HAVING AN IN-HOUSE LAB?**

2008 FIGURES. – Jackson Thyroid & Endocrine Clinic, PLLC

<table>
<thead>
<tr>
<th>LAB TEST</th>
<th>#PERFORMED</th>
<th>YOUR COST</th>
<th>REIMB.</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSH</td>
<td>3217 @ $1.40</td>
<td>$4,503.80</td>
<td>$152,775.00</td>
</tr>
<tr>
<td>FREE T4</td>
<td>3216 @ $2.25</td>
<td>$7,236.00</td>
<td>$98,455.00</td>
</tr>
<tr>
<td>Calcium</td>
<td>761 @ $.17</td>
<td>$129.00</td>
<td>$8,302.00</td>
</tr>
<tr>
<td>HCG(Kit)</td>
<td>86 @ $1.19</td>
<td>$102.30</td>
<td>$1,892.00</td>
</tr>
</tbody>
</table>
HOW PROFITABLE IS IT FOR YOU TO BILL FOR YOUR SENDOUT LABS??

2008 FIGURES. Jackson Thyroid & Endocrine Clinic, PLLC

<table>
<thead>
<tr>
<th>LAB TEST</th>
<th>#PERFORMED</th>
<th>FEE</th>
<th>REIMB.</th>
</tr>
</thead>
<tbody>
<tr>
<td>TPO</td>
<td>601@</td>
<td>$7212.00</td>
<td>$22,838.00</td>
</tr>
<tr>
<td>TG</td>
<td>382@</td>
<td>$8404.00</td>
<td>$35,908.00</td>
</tr>
<tr>
<td>TSI</td>
<td>162@</td>
<td>$9290.00</td>
<td>$23,166.00</td>
</tr>
<tr>
<td>TSHRab</td>
<td>164@</td>
<td>$8175.40</td>
<td>$6,396.00</td>
</tr>
<tr>
<td>CBC</td>
<td>254@</td>
<td>$825.00</td>
<td>$5,334.00</td>
</tr>
<tr>
<td>COMP</td>
<td>200@</td>
<td>$800</td>
<td>$9,400.00</td>
</tr>
</tbody>
</table>
SO WHY DOESN’T EVERYONE HAVE A LAB?????

**Other Costs Are Significant!!!!**

- Lab Supplies: $45,537.34
- Service Agreement: $15,000.00
- CLIA: $188.00
- MLE Surveys: $363.00
- Calibration of Equipment: $176.55
- Validation standards: $946.52
- Salaries: $73,320.00
- Reference Lab: $95,880.91
- **Total Costs**: $246,383.45
On site Microscopy– FNA Adequacy
Another vital laboratory function.

- **FNA adequacy does make a difference in the “point of care” results.**
- **Follicular cells seen in node, then STOP STICKING.**
A GOOD MEDICAL TECHNOLOGIST IS KEY TO THE WHOLE OPERATION.

FORGET THE MONEY MADE ON LABS, I COULD PAY HER SALARY WITH FNA ADEQUACY BILLING ALONE!!!
WHAT SHOULD YOU NAME YOUR CLINIC?

- Let them know what you do.
- Have **THYROID** in your clinic name.
- **If you have** **DIABETES** **in your clinic name, you will continue to be a diabetes doctor.**
Set yourself apart.

- **WHAT MAKES YOU DIFFERENT FROM THE OTHER ENDOCRINOLOGISTS IN YOUR TOWN??**
- Be the point person.
- **Be visionary, not reactionary.**
- You may not be able to start off with all of these things, but have a defined plan.
“DO SOMETHING YOU LOVE AND YOU WILL NEVER WORK A DAY IN YOUR LIFE.”

Confucius
“Do the work you love, and you will find joy in it”

• Lawrence Welk