TB NURSE NETWORK MEETING

Wednesday July 20, 2016

10:00-12:00 PM

Conference call in number: 1-888-557-8511

Passcode: 2544873

Agenda

Please Remember to Mute Your Phones

Announcements (10 min)

- Archived and upcoming webinars
- Upcoming meetings and events
- New educational materials on our website

Discordant TST and IGRA Test Results (30 min)

- Peter Davidson, PhD; MDHHS

Open Forum: LTBI Billing (30 min)

Close and Adjourn

Announcements

Next TBNN meeting

- Wednesday October 19th, 2016
- 10-12 PM EST
- Online webinar and conference call

Resources Needed!

- Interpreter & translation services used
- Policies on:
  - Video DOT
  - Incentive and enabler use
- Please email/fax information to Helen McGuirk
  - mcguirkh@Michigan.gov
  - Fax: 517-335-8263

Recently Archived Webinars

Mayo Clinic Center for Tuberculosis

1. "CDC MDR TB ENM Webinar Series: MDR-CNS"
   - Archived here
2. "TB in the Federal Corrections System: Status, Challenges, and Opportunities"
   - Archived here

Southeastern National Tuberculosis Center (SNTC)

1. "Learning From the Front Lines: Celebrating 10 Years of the Medical Consultation Database"
   - Archived here
2. "Changing TB Isolation Practices: New Guidelines for Molecular Testing"
   - Will be archived here, presented on 7/20/16

Curry International Tuberculosis Center

1. "INH and Rifapentine Treatment for LTBI: Expert Opinions about 3HP Utilization"
   - Archived here

Upcoming Webinars

SNTC & Curry International TB Center

1. "GeneXpert: Examples From the Field"
    - 7/27/16, 1-2:30 PM Eastern
    - Register here

Mayo Clinic Center for Tuberculosis

1. "Tuberculosis and Biologics"
    - 9/14/16, 1-2 PM Eastern
    - Registration not open yet

New Materials on our Website

MDHHS 2016 TB Nursing Certification

- Presentations (Adobe PDF) www.michigan.gov/tb --> scroll to "educational events"

Upcoming Events

Tri-State TB Clinical Intensive

- Audience: Physicians, NPs/PAs, RNs, Infection Control Practitioners, and other healthcare professionals working in Michigan, Indiana, and Ohio
- Dates: September 29-30, 2016
- Location: Dearborn, MI, Arab American History Museum
- Registration: Free, online, will open in August, more info to follow
- Information:
  - tbcenter@mayo.edu
  - ‘Save The Date’ will be released late July

DISCORDANT TST & IGRA RESULTS

PETER DAVIDSON

MI TB NURSING CERTIFICATION WORKSHOP

JUNE 28, 2016

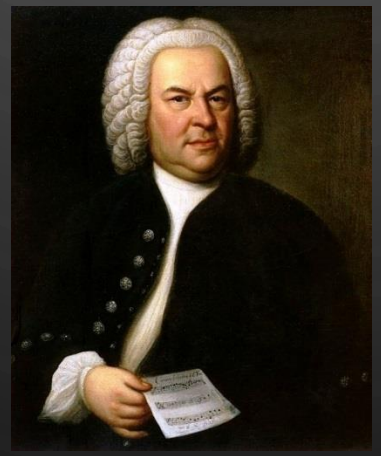
CONTENT

- DISCUSS SCENARIOS IN WHICH DISCORDANT TST AND IGRA RESULTS ARE LIKELY TO BE ENCOUNTERED
- DISCUSS COMMON PROBLEMS WHEN IGRA AND TST ARE USED IN THE SAME PERSON
- PROVIDE UPDATED GUIDANCE FOR INTERPRETING DISCORDANT TST AND IGRA RESULTS

AND WHAT TO DO NEXT!

A NOTE ON DISCORDANCE

- DISCORDANCE: (1) BEING AT VARIANCE; DISAGREEING; INCONGRUOUS. (2) DISAGREEABLE TO THE EAR; DISSONANT; HARSH.
- WE WILL FOCUS ON #1 (MAY CAUSE #2 IN YOUR OFFICE)
- WHICH TEST IS DISCORDANT?
  - TST V IGRA
  - IGRA V IGRA
  - TST V TST



https://upload.wikimedia.org/wikipedia/commons/6/6a/Johann_Sebastian_Bach.jpg

http://www.celebrityrockstarguitars.com/rock/rhoads_files/randyrhoads_color.jpg

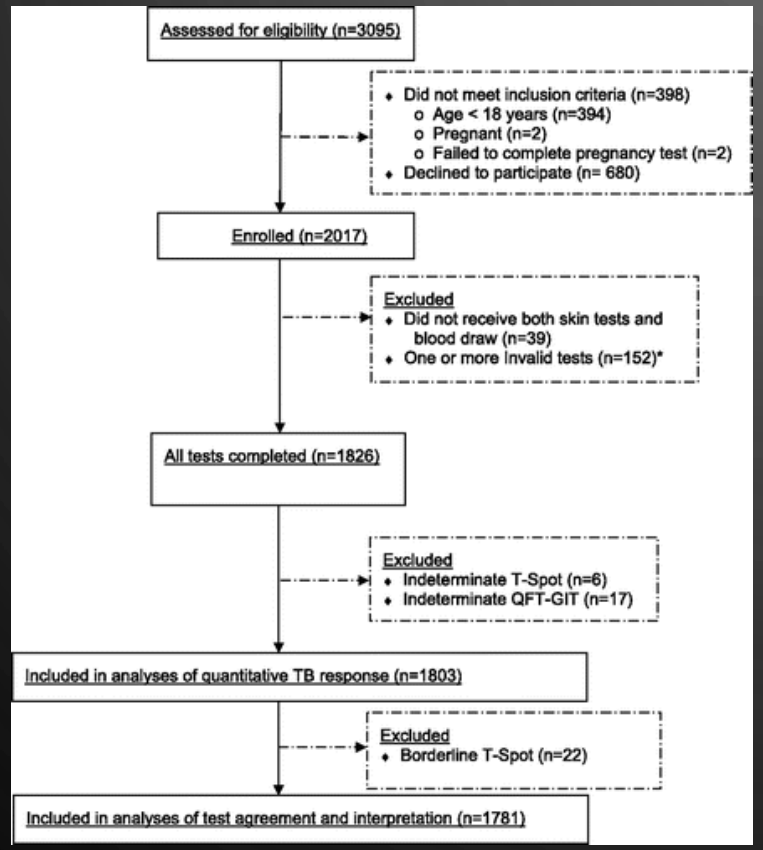
DISCORDANT RESULTS ARE LIKELY WHEN…

- PERSON(S) AT LOW RISK FOR TB INFECTION ARE TESTED FOR TB MORE THAN ONCE
- DIFFERENT TEST METHODS (TST/IGRA) ARE USED ON THE SAME PERSON (DELIBERATE OR ACCIDENTAL)
  - EXACERBATED IF PERSON IS AT LOW RISK FOR TB INFECTION
- OPERATOR ERROR
  - TECHNIQUE
  - SPECIMEN HANDLING OR PROCESSING
  - TUBE OR REAGENT STORAGE

VARIANCE THAT MAY CONTRIBUTE TO DISCORDANCE

- PERSON
  - TIME SINCE INFECTION IN THE ABSENCE OF FURTHER EXPOSURE TO *M. TUBERCULOSIS* ANTIGEN
  - RECENT PREVIOUS TUBERCULIN SKIN TESTING (BOOSTING AN IGRA RESPONSE)
  - IMMUNOSUPPRESSIVE MEDICATIONS (*E.G.* CORTICOSTEROIDS)
  - IMMUNOSUPPRESSIVE DISEASES (*E.G.* HIV)
  - RECENT LIVE VIRAL VACCINATION OR ILLNESS
  - LYMPHOPENIA
- TEST
  - MANUFACTURING ISSUES (IGRA CONTROL TUBES, ANTIGEN COATING)

MANCUSO (2012): TST VS QFT-G VS T.SPOT



- MILITARY RECRUITS, ENTRY MEDICAL SCREEN, APRIL – JUNE, 2009
- RISK FACTOR QUESTIONNAIRE PLUS:
  - TST
  - QFT-G
  - T.SPOT
- SPOILER (NECESSARY)
  - 21 HIGH-RISK
  - 409 MEDIUM-RISK
  - 1,373 LOW-RISK

MANCUSO (2012): TST VS QFT-G VS T.SPOT

	TST Positive	TST Negative	Total
T.SPOT Positive	15 (0.8%)	19 (1.1%)	34 (1.9%)
T.SPOT Negative	33 (1.9%)	1,714 (96.2%) †	1,747 (98.1%)
Total	48 (2.7%)	1,733 (97.3%)	1,781

LOW CONCORDANCE
OF POSITIVES
15/48 = 31.3%

HIGH CONCORDANCE
OF NEGATIVES
1714/1733 = 98.9%

† Includes 23 subjects with borderline TB response of five spots (11), six spots (11), or seven spots (one).

MANCUSO (2012): TST VS QFT-G VS T.SPOT

	TST Positive	TST Negative	Total
QFT-G Positive	11 (0.6%)	25 (1.4%)	36 (2%)
QFT-G Negative	37 (2.1%)	1,708 (95.9%)	1,745 (98%)
Total	48 (2.7%)	1,733 (97.3%)	1,781

LOW CONCORDANCE
OF POSITIVES
11/48 = 22.9%

HIGH CONCORDANCE
OF NEGATIVES
1708/1733 = 98.6%

MANCUSO (2012): TST VS QFT-G VS T.SPOT

	QFT-G Positive	QFT-G Negative	Total
T.SPOT Positive	14 (0.8%)	20 (1.1%)	34 (1.9%)
T.SPOT Negative	22 (1.2%)	1,725 (96.9%)	1,747 (98.1%)
Total	36 (2%)	1745 (98%)	1,781

LOW CONCORDANCE OF POSITIVES
14/36 = 38.9%
* Although higher than either v TST

HIGH CONCORDANCE OF NEGATIVES
1725/1745 = 98.9%

MANCUSO (2012): TST VS QFT-G VS T.SPOT

	Quantitative TST Result				Quantitative QFT-G Result			Quantitative T.SPOT Result		
Risk Level	0 – 4 mm	5 – 9 mm	10 – 14 mm	> 15 mm	< 0.35	0.35 – 0.99	> 1	< 4 spots	5 – 7 spots	> 8 spots
High (5 mm)	18 (85.7%)	**1 (4.8%)**	**1 (4.8%)**	**1 (4.8%)**	18 (85.7%)	**2 (9.5%)**	**1 (4.8%)**	20 (95.2%)	0	**1 (4.8%)**
Medium (10 mm)	362 (88.5%)	10 (2.4%)	21 (5.1%)	16 (3.9%)	392 (95.8%)	7 (1.7%)	10 (2.4%)	391 (95.6%)	3 (0.7%)	15 (3.7%)
Low (15 mm)	1,332 (97%)	21 (1.5%)	10 (0.7%)	10 (0.7%)	1,356 (98.8%)	13 (1%)	4 (0.3%)	1,336 (97.3%)	19 (1.4%)	18 (1.3%)

1. Concordance is highest in High-Risk pts (3:3:1)

MANCUSO (2012): TST VS QFT-G VS T.SPOT

	Quantitative TST Result				Quantitative QFT-G Result			Quantitative T.SPOT Result		
Risk Level	0 – 4 mm	5 – 9 mm	10 – 14 mm	> 15 mm	< 0.35	0.35 – 0.99	> 1	< 4 spots	5 – 7 spots	> 8 spots
High (5 mm)	18 (85.7%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	18 (85.7%)	2 (9.5%)	1 (4.8%)	20 (95.2%)	0	1 (4.8%)
Medium (10 mm)	362 (88.5%)	10 (2.4%)	21 (5.1%)	16 (3.9%)	392 (95.8%)	7 (1.7%)	10 (2.4%)	391 (95.6%)	3 (0.7%)	15 (3.7%)
Low (15 mm)	1,332 (97%)	21 (1.5%)	10 (0.7%)	**10 (0.7%)**	1,356 (98.8%)	**13 (1%)**	**4 (0.3%)**	1,336 (97.3%)	19 (1.4%)	**18 (1.3%)**

2. Concordance is weak in Low-Risk pts (10:17:18)
   * better between QFT & T.SPOT (17:18)

MANCUSO (2012): TST VS QFT-G VS T.SPOT

	Quantitative TST Result				Quantitative QFT-G Result			Quantitative T.SPOT Result		
Risk Level	0 – 4 mm	5 – 9 mm	10 – 14 mm	> 15 mm	< 0.35	0.35 – 0.99	> 1	< 4 spots	5 – 7 spots	> 8 spots
High (5 mm)	18 (85.7%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	18 (85.7%)	2 (9.5%)	1 (4.8%)	20 (95.2%)	0	1 (4.8%)
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3. Concordance is horrible in Medium-Risk pts (37:17:15)
   * better between QFT & T.SPOT (17:15)

https://www.youtube.com/watch?v=Ms3hhd4ULLU

MANCUSO (2012): OVERALL TEST AGREEMENT

Test Results	High-Risk (5 mm) n=21	Medium-Risk (10 mm) n=406	Low-Risk (15 mm) n=1,354
All tests negative	16 (1%)	359 (21.2%)	1,318 (77.9%)
One test positive	**4 (5.9%)**	33 (48.5%)	31 (45.6%)
TST only	2 (6.3%)	23 (71.9%)	7 (21.9%)
QFT-G only	2 (9.5%)	8 (38.1%)	11 (52.4%)
T.SPOT only	0 (0%)	2 (13.3%)	13 (86.7%)
Two tests positive	**0 (0%)**	7 (70%)	3 (30%)
TST and QFT-G	0 (0%)	1 (100%)	0 (0%)
TST and T.SPOT	0 (0%)	5 (100%)	0 (0%)
QFT-G and T.SPOT	0 (0%)	1 (25%)	3 (75%)
All three tests positive	**1 (10%)**	7 (70%)	2 (20%)

Interpreting in Rows

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QFT-G and T.SPOT	0 (0%)	1 (25%)	3 (75%)
All three tests positive	1 (10%)	7 (70%)	2 (20%)

1. Majority of 'all negatives' are in Low-Risk pts
   * Expected

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All three tests positive	1 (10%)	7 (70%)	2 (20%)

2. 'One positives' are roughly even between Med- and Low-Risk; individual positives mostly in Low-Risk, except for TST

* Not Expected

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QFT-G and T.SPOT	0 (0%)	1 (25%)	3 (75%)
All three tests positive	1 (10%)	7 (70%)	2 (20%)

3. 'Two positives' most common in Medium-Risk, and most likely between TST and T.SPOT
   * Expected? Why? Who knows?

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All three tests positive	1 (10%)	**7 (70%)**	2 (20%)

4. 'All three positive' generally unlikely, and most often in Medium-Risk
   * What the heck?

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QFT-G and T.SPOT	0 (0%)	1 (25%)	3 (75%)
All three tests positive	**1 (10%)**	7 (70%)	2 (20%)

5. No test, alone or in combination, was often positive among High-Risk
   *ARRGHGH!!!

ARE WE DISCORDANT YET?

http://l.yimg.com/os/publish-images/sports/2014-05-01/3fa90770-d139-11e3-ba0e-6fe11e85aa34_133606027.jpg

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QFT-G only	2 (50%)	8 (24.2%)	11 (35.5%)
T.SPOT only	0 (0%)	2 (6.1%)	13 (41.9%)
Two tests positive	0 (0%)	7 (1.7%)	3 (0.2%)
TST and QFT-G	0 (0%)	1 (14.3%)	0 (0%)
TST and T.SPOT	0 (0%)	5 (71.4%)	0 (0%)
QFT-G and T.SPOT	0 (0%)	1 (14.3%)	3 (100%)
All three tests positive	1 (4.8%)	7 (1.7%)	2 (0.1%)

Interpreting in Columns…Things look a little different

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1. Proportion of 'all negative' increases as Risk level decreases
   * Expected

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All three tests positive	1 (4.8%)	7 (1.7%)	2 (0.1%)

2. Proportion of 'one positive' decreases as Risk level decreases
   * Expected (but odd distribution in Medium- and Low-Risk

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QFT-G and T.SPOT	0 (0%)	1 (14.3%)	3 (100%)
All three tests positive	1 (4.8%)	7 (1.7%)	2 (0.1%)

3. No ‘two positives’ in High-Risk
   * Unexpected

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QFT-G and T.SPOT	0 (0%)	1 (14.3%)	3 (100%)
All three tests positive	1 (**4.8%**)	7 (**1.7%**)	2 (**0.1%**)

4. Highest proportion of 'all positive' in High-Risk, and proportion decreases as Risk level decreases

   * Expected…Yes!

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Could pts have been misclassified in Risk level? Pt recall or response?
Weakness or gaps in questionnaire?

WHAT DOES MANCUSO'S PAPER TELL US?

- IN GENERAL, DO NOT EXPECT CONCORDANT TB TEST RESULTS
  - MORE LIKELY IN HIGH-RISK PATIENTS, BUT RARE EVEN THEN
- REMEMBER THAT TST AND IGRAS ARE VERY DIFFERENT TESTS
  - THEY ARE MEASURING DIFFERENT PARTS OF THE IMMUNE SYSTEM
  - AS DR. KISSNER SHOWED, THE QUANTITATIVE VALUES FOR IGRAS ARE CRUCIAL TO UNDERSTAND THE RESULT

CASE EXAMPLE

- 19 YR F, US-BORN
- PARENTS BORN IN INDIA
- TRIPS TO INDIA, LASTING ~ 1 MONTH/TRIP AT AGES:
    - 6 MONTHS OLD
    - 11 MONTHS OLD
    - 3 YEARS OLD

CASE EXAMPLE

- MULTIPLE TB TESTS
  - TST 5/19/2000 (4 YRS): **20 MM**
  - QFT-G 1/31/2015 (18-19 YRS): **NEG**
  - QFT-G 2/2/2015: **POS**
  - T.SPOT 4/6/2015: **BORDERLINE**
- 2015 (18-19 YRS) PATIENT HAD EYE IRRITATION/INFECTION, TESTED DUE TO SUSPECT OCULAR TB
  - ALSO HAD AN UNSPECIFIED IMMUNE SYSTEM DISORDER (BELIEVED TO BE IMMUNOSUPPRESSED)
- DIAGNOSIS OF OCULAR TB AND TREATED FOR 6 MO

GUIDANCE FOR INTERPRETING DISCORDANT TST AND IGRA RESULTS

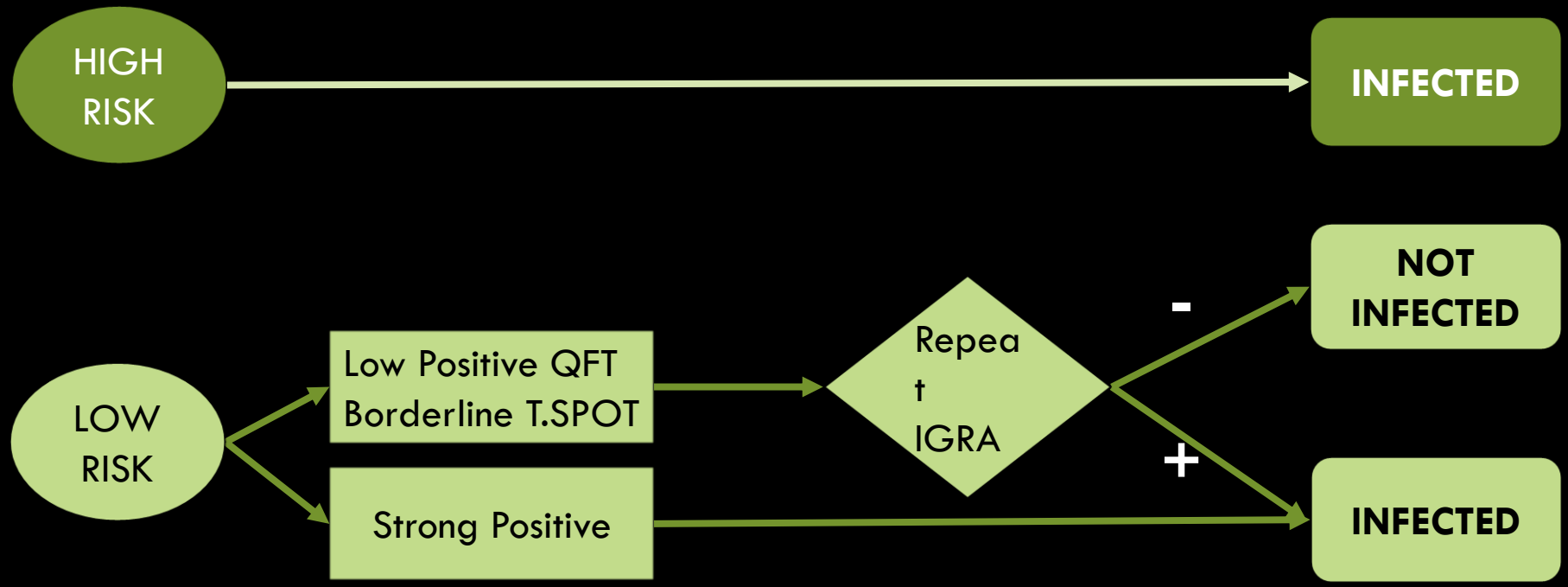
- THINK VERY CAREFULLY ABOUT HOW YOU WILL PROCEED
- NEVER RETEST A PATIENT TO REFUTE A PRIOR RESULT
- THOROUGHLY ASSESS AND DOCUMENT ALL RISK FACTORS
  - RISK FOR INFECTION HELPS DETERMINE WHICH RESULT TO BELIEVE
  - RISK FOR PROGRESSION HELPS DETERMINE WHETHER TO ORDER ANOTHER TEST
- CLINICAL DECISION IS NECESSARY, AND MUST ACCOUNT FOR PATIENT'S RISK FACTORS

KNOW THE RISK – HIGH VS LOW

- NTCA GUIDELINES EMPHASIZE RISK OF PROGRESSION FROM INFECTION TO DISEASE
- ONLY TWO RISK LEVELS: HIGH & LOW
  - HIGH RISK:
    - HIV/AIDS
    - PERSONS BEING CONSIDERED FOR IMMUNOSUPPRESSIVE THERAPY
    - PRE-TRANSPLANTATION
    - SILICOSIS
    - END STAGE RENAL DISEASE
    - POORLY-CONTROLLED DIABETES MELLITUS

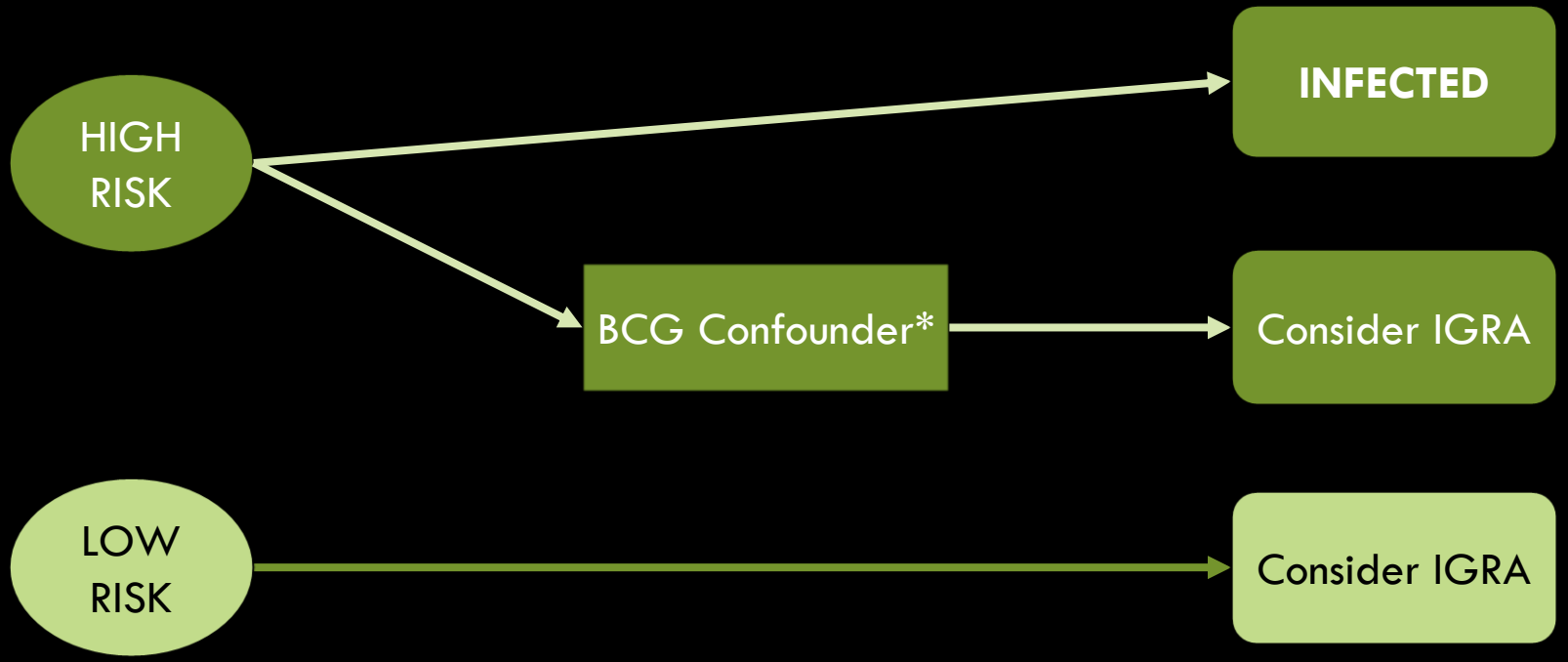
WHAT TO DO IF…

IGRA: POSITIVE/BORDERLINE
TST: UNKNOWN/NOT DONE/NEGATIVE



WHAT TO DO IF…

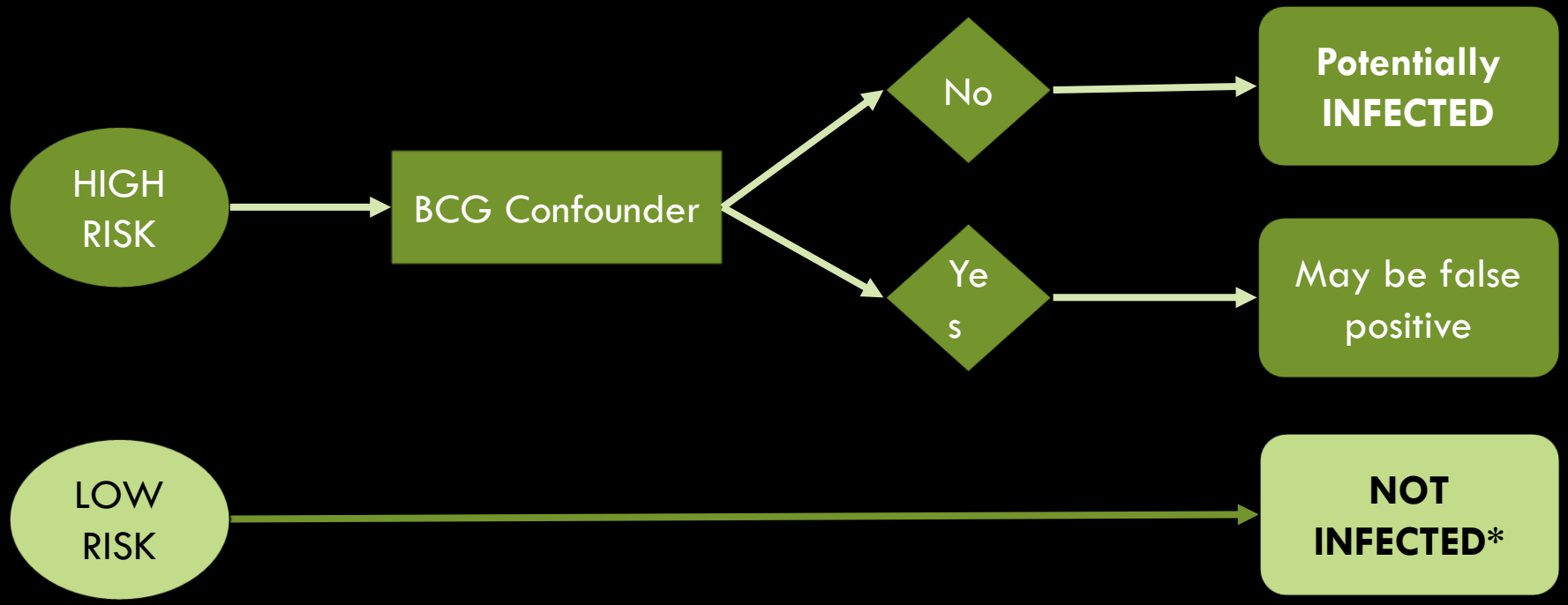
IGRA: UNKNOWN/NOT DONE
TST: POSITIVE



* IF TST WAS PLACED W/IN 10 YRS OF BCG

WHAT TO DO IF…

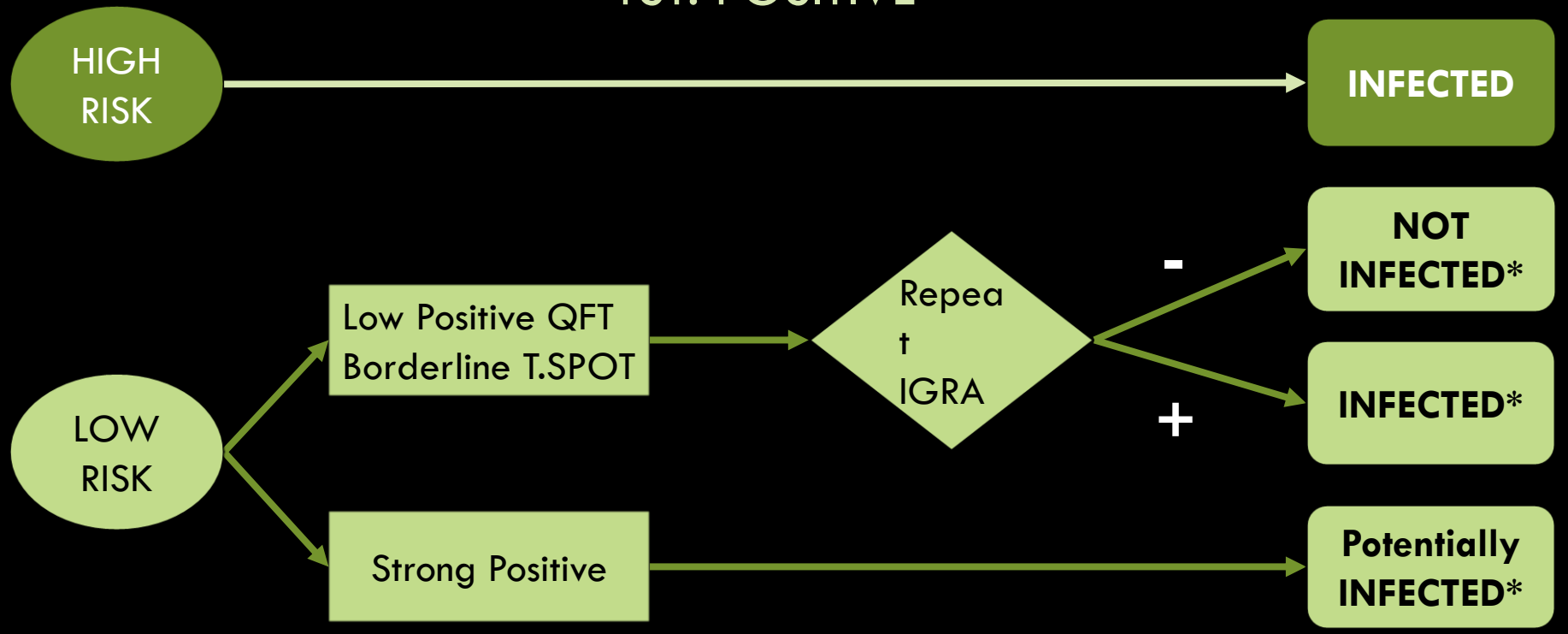
IGRA: NEGATIVE
TST: POSITIVE



* TST likely false positive, recommend IGRA for future testing

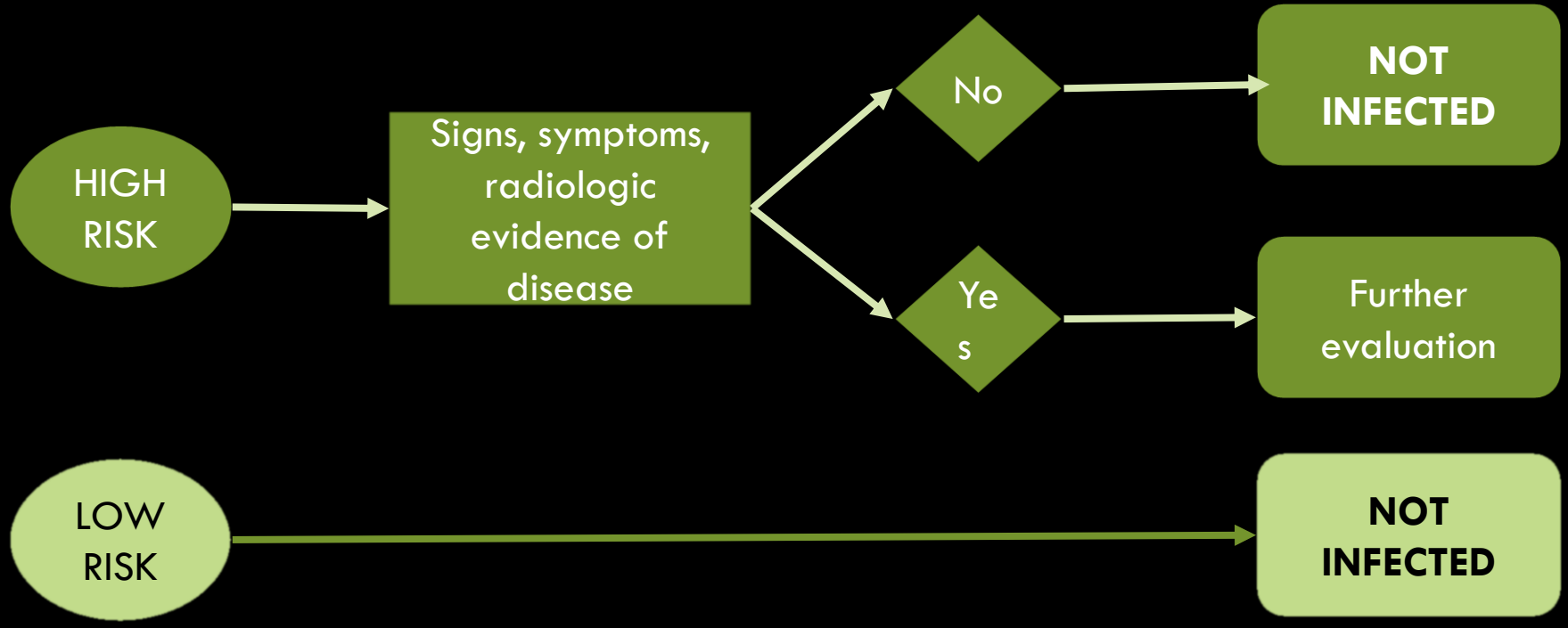
WHAT TO DO IF…

IGRA: POSITIVE
TST: POSITIVE



* Consider risks/benefits of treatment vs evaluation

WHAT TO DO IF…
IGRA: NEGATIVE
TST: NEGATIVE



SUMMARY

- MANY SCENARIOS CAN GIVE RISE TO DISCORDANT TB TEST RESULTS
- VARIANCES IN PERSON BEING TESTED, AND COMPONENTS OF THE TESTS THEMSELVES, CONTRIBUTE TO DISCORDANT RESULTS
- THE TST AND IGRAS ARE FUNDAMENTALLY DIFFERENT TESTS, WHICH MEASURE DIFFERENT PARTS OF THE IMMUNE SYSTEM
- UNDERSTANDING AND INTERPRETING TB TEST RESULTS REQUIRES:
  - COMPLETE KNOWLEDGE OF PERSON'S RISK FOR INFECTION AND PROGRESSION
  - QUANTITATIVE DATA FROM THE IGRA REPORT

CONCLUSIONS

- DISCORDANT TB TEST RESULTS SHOULD BE EXPECTED AND PLANNED FOR
  - FAR MORE LIKELY IN LOW-RISK PERSONS
- A DECISION TO **TEST** MUST BE A DECISION TO **THINK**
  - PERSON'S RISK FACTORS
  - STRATEGY IN ADVANCE FOR WHEN TO REPEAT TB TEST, AND HOW TO INTERPRET
- IGRAS CAN REQUIRE AS MUCH INTERPRETATION AS TST
- NO TB TEST IS PERFECT, AND NO SINGLE TEST SHOULD BE USED TO REFUTE PRIOR RESULTS

THANK YOU!

QUESTIONS?

REFERENCES

- MANCUSO (2012) HTTP://WWW.ATSJOURNALS.ORG/DOI/FULL/10.1164/RCCM.201107-1244OC#.V18SFBVR_IU
- POLLOCK (2008) HTTP://WWW.NCBI.NLM.NIH.GOV/PUBMED/18713053
- NTCA (2016, PENDING) RECOMMENDATIONS & BEST PRACTICES FOR THE USE AND INTERPRETATION OF IGRAS

Open Forum: Billing for LTBI Services

1. Does your LHD bill insurance for LTBI services?
    - What services/activities?
        - TST or IGRA, CXR, liver functions, meds, time, etc.

2. Workgroup to see what states are successfully doing this

Thank you!

- Meeting notes will be sent to everyone on the TB Nurse Network list

- If you have questions/comments regarding TBNN, please contact:

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