

# Why 1.5 is the New 4.0 for the PCP?

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# PSA Screening Recommendations of Major Societies

Organization	Who To Screen	Screening Interval
USPSTF, 2012	Should not be offered, consider shared decision making (SDM)	na
AUA, 2013	55-69 y or $\geq 70$ with 10 to 15 y life expectancy, use SDM; $< 55$ y individualize approach	Consider 2 y interval over annual; may individualize depending on initial level
ASCO, 2012	Men with life expectancy $> 10$ y, SDM	none
ACS, 2010	$>50$ y at average risk with 10 y life expectancy use SDM; 45 y high risk, 40 y very high risk	Annual if $\geq 2.5$ ng/ml; biannual if $< 2.5$ ng/ml Biopsy if $> 4$ ng/dl, individualize 2.5-4 ng/ml
ACP, 2013	$>50$ y at average risk with 10 y life expectancy use SDM; 45 y high risk, 40 y very high risk	Consider longer intervals than yearly
EAU, 2013	Baseline PSA $\geq 40$ – 45 y	2-4 y with PSA $> 1\mu\text{g/L}$ at 45-59 y and up to 8 y if PSA $< 1\mu\text{g/L}$

# Tenets of Shared Decision Making

- Provision of information
  - Balanced and evidence based
  - Harms and benefits of each option
- Elicitation of patient's perspective
  - Asking about prior experiences
  - Understanding and discussing concerns
  - Delineating preferences regarding screening options
- Guiding final decision making (without directing)

# The Bad News: PSA is not a great Test

- PSA is prostate specific. Elevations occur with
  - Cancer (poor sensitivity)
  - Benign prostatic hypertrophy
  - Prostatitis
    - Antibiotics decrease PSA in 30% if infected
  - Trauma, instrumentation
  - Does not increase with sex or DRE
- 15% variation week to week
- Assay variability up to 20%

# The Dilemma of a Limited Test

- Serum PSA has a high false positive rate
- Over 1 million prostate biopsies performed annually in the US
  - 75% biopsies have low-grade indolent (Gleason 6) or no prostate cancer
  - Serious complications of biopsies include infection and hospitalization
- Following the USPSTF recommendations misses an opportunity to detect and treat men with high grade prostate cancer (Gleason grade  $\geq 7$ )

# Who is Ordering PSA tests?

Specialty	Percent
Internal Medicine	64.9
Family Medicine	23.7
Urology	6.1
Hem/Onc	1.3

# The Annual Check Up Form

Patient Name \_\_\_\_\_ Date \_\_\_\_\_  
 LMP \_\_\_\_\_ BP \_\_\_\_\_ Ht \_\_\_\_\_ Wt \_\_\_\_\_ Pulse \_\_\_\_\_ Temp \_\_\_\_\_  
 Allergies \_\_\_\_\_ PHQ score \_\_\_\_\_  
 Chief Complaint \_\_\_\_\_ BMI \_\_\_\_\_

Advance Directive Discussed Yes No

PAST MEDICAL HISTORY		PAST SURGICAL HISTORY	
1. _____	6. _____	1. _____	_____
2. _____	7. _____	2. _____	_____
3. _____	8. _____	3. _____	_____
4. _____	9. _____	4. _____	_____
5. _____	10. _____	5. _____	_____

MEDICATIONS		PATIENT EDUCATION	
1. _____	6. _____	1. <u>SELF EXAM - BREAST</u>	_____
2. _____	7. _____	2. <u>SELF EXAM -TESTICULAR</u>	_____
3. _____	8. _____	3. <u>NUTRITION/DIET</u>	_____
4. _____	9. _____	4. <u>SAFETY/INJURY PREVENTION</u>	_____
5. _____	10. _____		

FAMILY HISTORY		REVIEW OF SYSTEMS	
MO _____	GEN _____	HEENT _____	_____
FA _____	HEME _____	CVS _____	_____
SIS ( ) _____	DISEASE _____	PULM _____	_____
BRO ( ) _____	NEURO _____	GI _____	_____
GRAND _____	SKIN _____	GU _____	_____
OTHER _____	ENDO _____	SEX _____	_____
	REPRO _____	MUSCUL _____	_____
	PSYCH _____		

Date of last PE \_\_\_\_\_

PHYSICAL		SOCIAL HISTORY	
General _____	_____	Tobacco: Current _____ Former _____ Never _____	_____
Integ _____	_____	Ready to Quit: Yes No	_____
HEENT _____	_____	Cessation Discussed: Yes No	_____
Neck/Bck _____	_____	Length of Discussion: 3-10min 10+min	_____
Cardiac _____	_____	ETOH: Yes No	_____
Chest _____	_____	Marital Status: M S D Widow	_____
Breasts _____	_____	Employed: Yes No Student	_____
Abdomen _____	_____	Type: _____	_____
Rectal _____	_____	<b>DIABETIC YES 🍏 NO 🍏</b>	_____
Prostate _____	_____	Last HgA1C _____ Bun _____ Cr _____	_____
Genitalia _____	_____	Last Eye _____ Last Foot _____	_____
EXT _____	_____	BS Range/Home _____ Micro _____	_____
Neuro _____	_____		

LABORATORY	
MAM _____	URINE _____
EKG _____	_____
PFT _____	_____
DEXA _____	Hb _____
Sig/Col _____	FBS _____
Flu Vac _____	Td/TDaP _____
Pneumo Vac _____	TSH _____
Chol _____	PSA _____

IMPRESSION	
1. _____	5. _____
2. _____	6. _____
3. _____	7. _____
4. _____	8. _____

PLAN	
1. _____	5. _____
2. _____	6. _____
3. _____	7. _____
4. _____	8. _____

# The PSA Dilemma

## What does the Value Mean?

**Velocity?**

**4.0?**

**Density?**

**Age Changes?**



# Shared Decision Making and PSA Testing: Results from a National Survey

Ever had a PSA  
test  
(ages 50 – 74)



Received all  
tenets of shared  
decision making



**10%**

**55%**

Understand  
some doctors  
recommend the  
test and others  
do not



**22%**

Informed that no  
one is sure if PSA  
testing saves lives



**14%**

# Understanding the Misunderstanding of the PSA

- Survey at the 2015 AAFP meeting in Denver
- 153 participants
  - 96 male
  - 49 female
  - 8 undeclared
- Years in practice 19.22
- Type of practice
  - 9 residents
  - 75 employed
  - 62 private
  - 7 undeclared

# Which of the following best describes your practice in terms of prostate cancer screening with PSA?

A. I do not recommend PSA based screening	35 (23%)
B. I start testing at age 45 years as a baseline level and tailor subsequent screening intervals based on baseline PSA	59 (39%)
C. I start testing at age 55 – 69 years of age or 70 years of age and older with a 10-15 year life expectancy	48 (31%)
A + B	2 (1%)
A + C	1 (<1%)
B + C	3 (2%)
No Answer	5 (3%)

# Which prostate cancer screening guideline or recommendations do you follow?

USPSTF - <b><i>Do not screen</i></b>	68 (44%)
AAFP - <b><i>Do not screen</i></b>	30 (20%)
AUA - <i>start testing at age 55 – 69 years of age or 70 years of age and older with a 10-15 year life expectancy</i>	13 (9%)
NCCN - <i>start testing at age 45 years as a baseline level and tailor subsequent screening intervals</i>	1 (<1%)
USPSTF + AAFP	12 (8%)
USPSTF + AUA	4 (3%)
USPSTF + NCCN	2 (1%)
NCCN + AUA	1 (<1%)
NONE	18 (12%)
“their own”	3 (2%)

For those who stated that “I do not recommend PSA based screening (n=35)”

***Which prostate cancer screening guideline or recommendations do you follow?***

USPSTF	19 (54%)
AAFP	3 (9%)
AUA	6
NCCN	0
USPSTF + AAFP	5 (14%)
USPSTF + AUA	1
USPSTF + NCCN + AUA	1
NCCN + AUA	1

**77%** knew  
the  
correct  
guideline

For those who stated that “I start testing at age 55 – 69 years of age or 70 years of age and older with a 10-15 year life expectancy (n=48)”

***Which prostate cancer screening guideline or recommendations do you follow?***

USPSTF	19
AAFP	13
AUA	5 (10%)
USPSTF + AAFP	6
USPSTF + AUA	1
No Answer	4

**10%** knew the  
**correct  
guideline**

**If you screen, at what age do you start screening? (n=118)**

Average	48.5
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**What is a suspicious PSA in a patient age 59? (n=100)**

Range	1.5 - 10
Average	4.099

**What is a suspicious PSA in a patient over 60? (n=93)**

Range	1.5 - 12
Average	4.68

# What is a PSA velocity that concerns you? (n=52)

Most common answer (n=10)	0.5
Second most common answer (n=5)	1/year
<b>See raw data as the other answers were all over the map</b>	



Do you believe that some prostate cancers are more aggressive or lethal than others?

Yes	149
No	4

If a patient had an abnormal PSA would a test that differentiates the chance of a low grade vs an aggressive tumor be of use to you (i.e. to refer to a specialist or not)?

Yes	134
No	12
No Answer	7

# How have the current guidelines impacted the use of PSA for screening?

**Men  $\geq$  50 yo reporting PSA screening in last 12 Months**

**2005 36.9**

**2008 40.6**

**2010 37.8**

**2012 30.8**

**Incidence of prostate cancer per 100,000 men  $\geq$  50 yo (n=446,009)**

**2005 534.9**

**2008 540.8**

**2010 505**

**2012 416.2**

# Changes in Prostate Cancer Detection

Number of men  $\geq 50$  diagnosed in US

**2011**

**213,563**

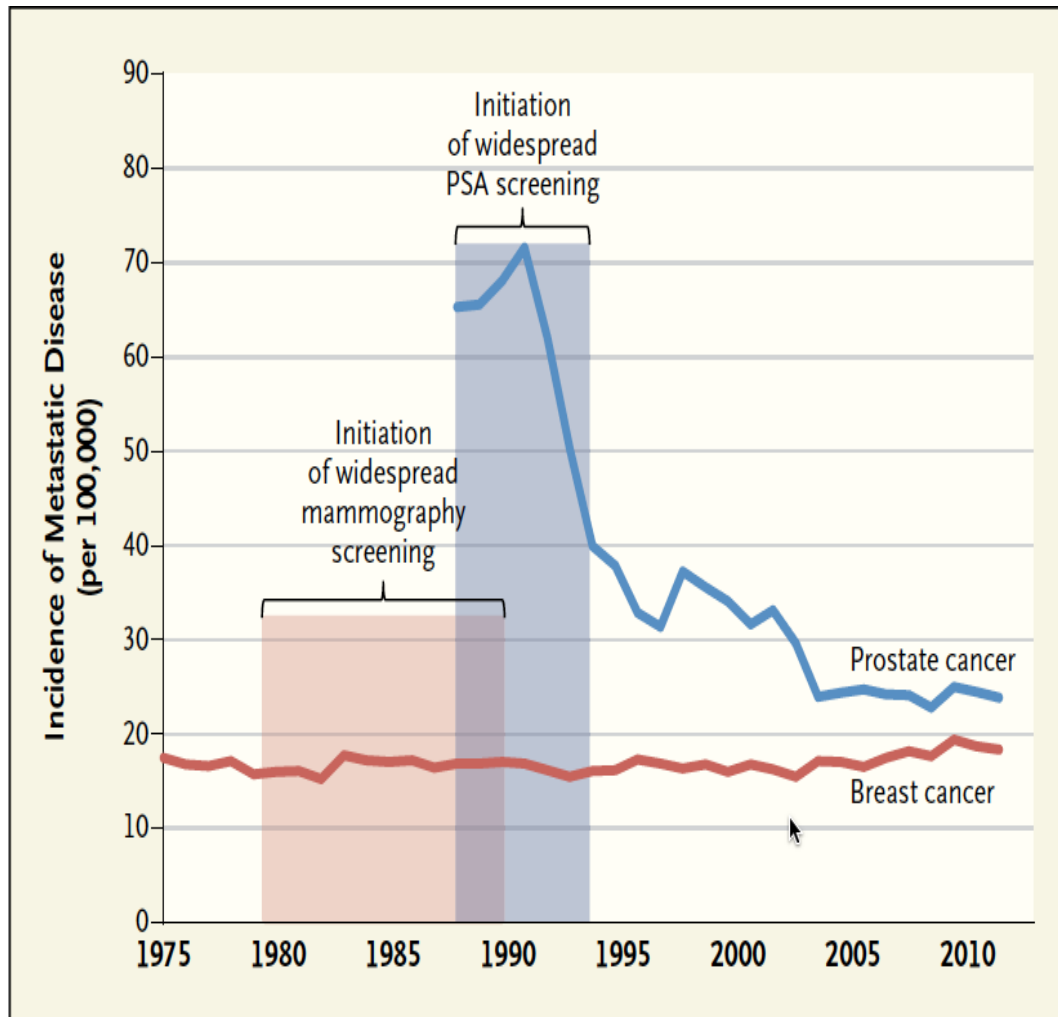
**2012**

**180,043**

# What if the Recommendations are Wrong?

“Both the incidence of early-stage prostate cancer and rates of PSA screening have declined and coincide with the 2012 USPSTF recommendation to omit PSA screening from routine primary care for men. Longer follow-up is needed to see whether these decreases are associated with trends in mortality”

# Dare We Go Back to the Pre-PSA Era?



With the introduction of PSA testing, death from prostate cancer was reduced by 20%, whereas metastatic disease was reduced by nearly half

# Screen or not screen?

Do I screen?

Does it matter?

I don't have time for this?

I don't have time to educate myself?

What is shared decision making?

Am I liable for overdiagnosis or underdiagnosis?



**Can We  
Simplify  
This?**



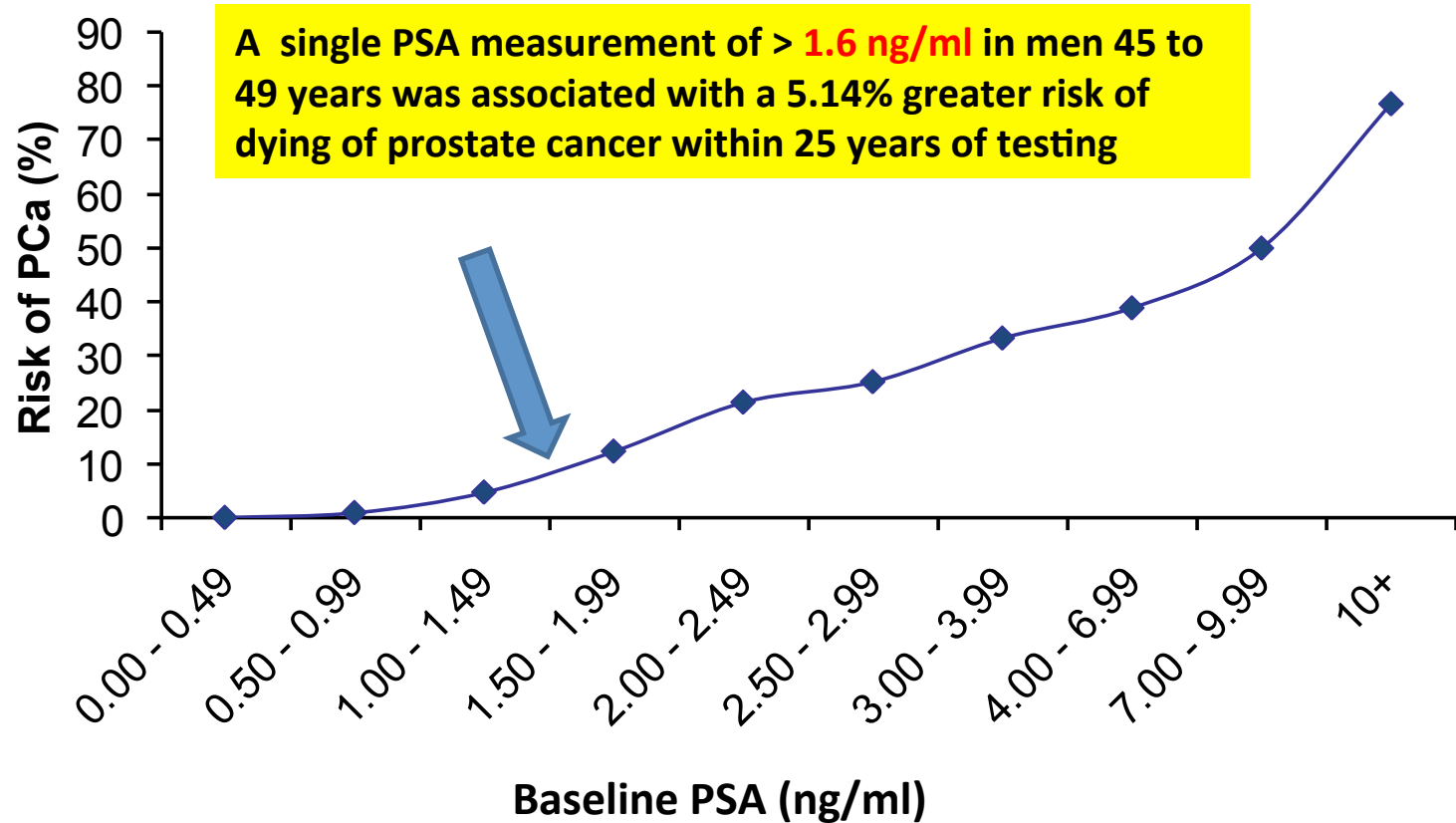
# Goals Needed to Simplify

- Decrease needless evaluations
- Don't make unnecessary patients
- Don't ask the PCP to counsel outside of their comfort zone
- Is it possible to just have one value?

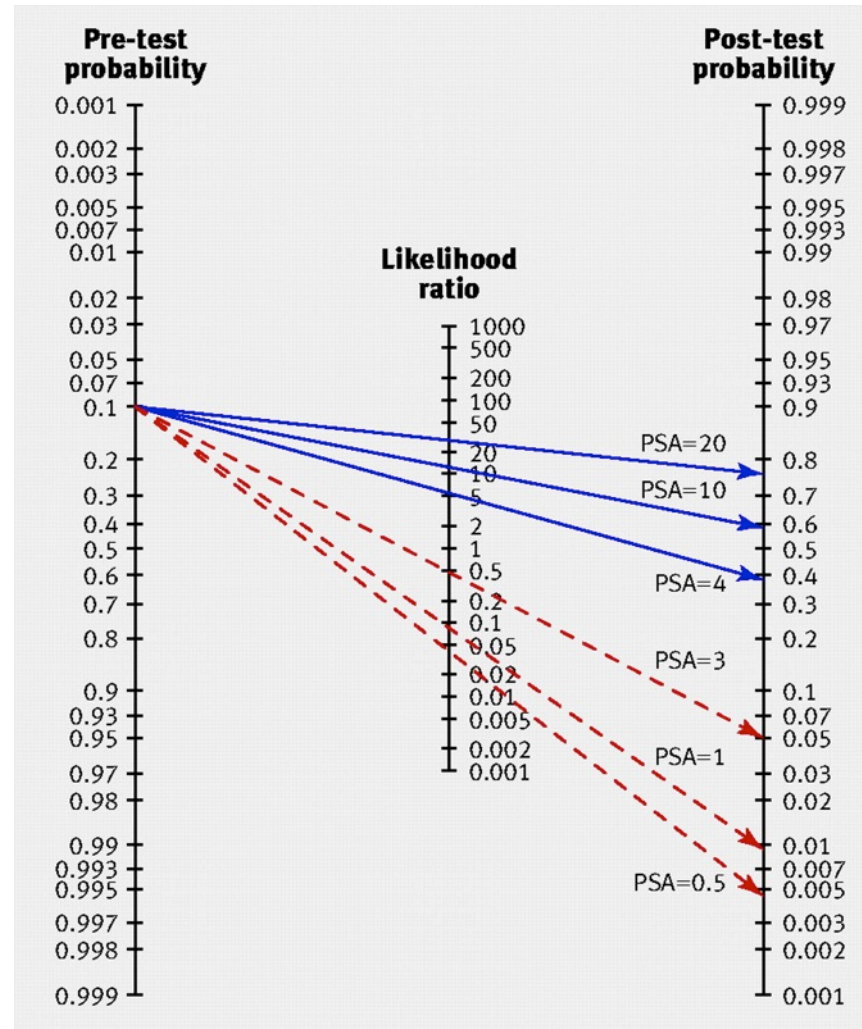


**Why is 1.5 ng/ml the only value  
I need to know?**

# Using PSA as a predictor



# Initial PSA Predicts Future Risk



Benny Holmström et al. BMJ 2009;339:bmj.b3537



# 5-year Diagnosis Rates Based on Initial PSA Level

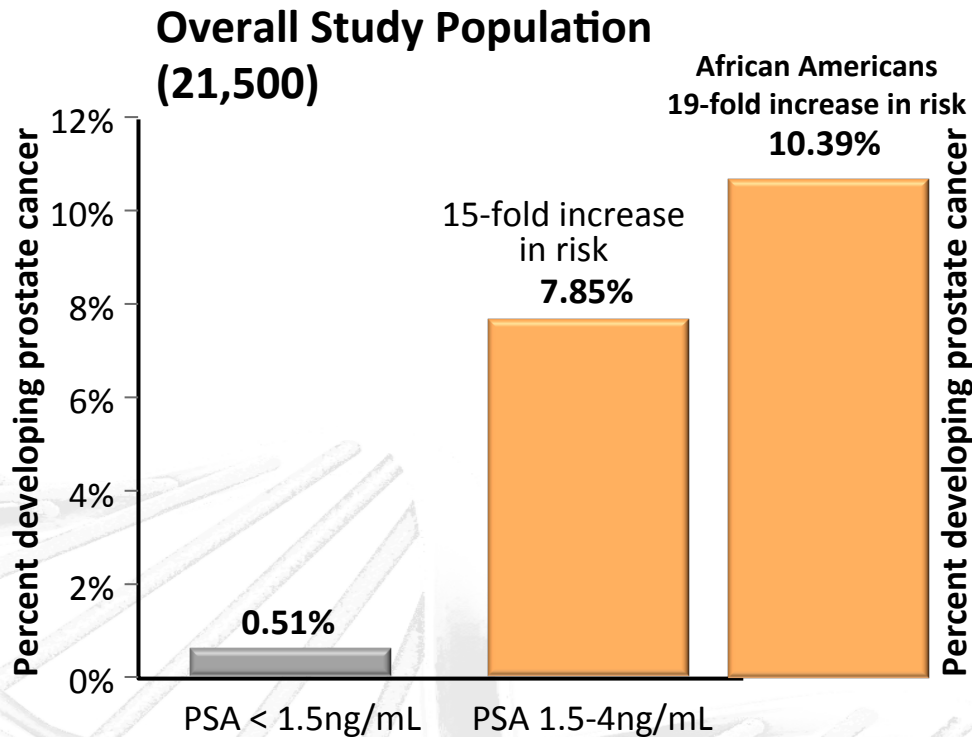
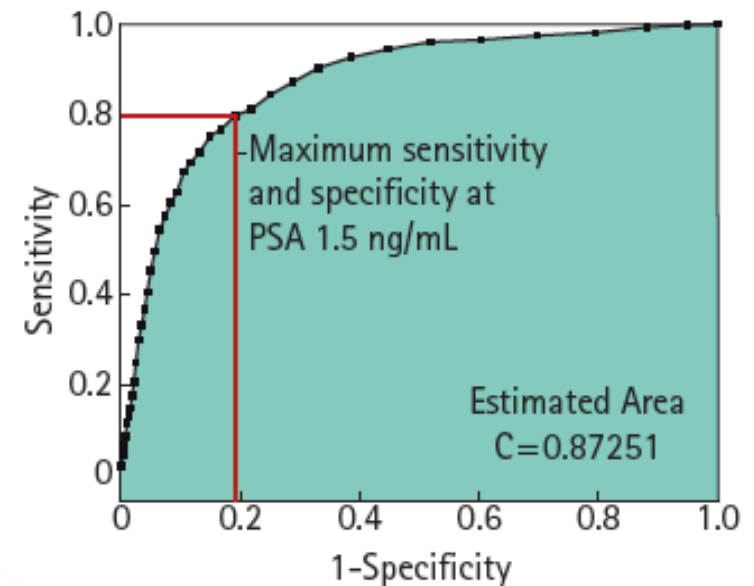


FIG. 2. Receiver operating characteristic curve for all patients.



**A first PSA test threshold of 1.5 - 4.0 ng/mL, represents the Early-Warning PSA Zone**  
**Patients with PSA  $\geq$ 1.5 ng/mL have an increased risk of developing PC**

Despite what everybody thinks,  
PSA levels above 1.5 ng/ml are  
not common

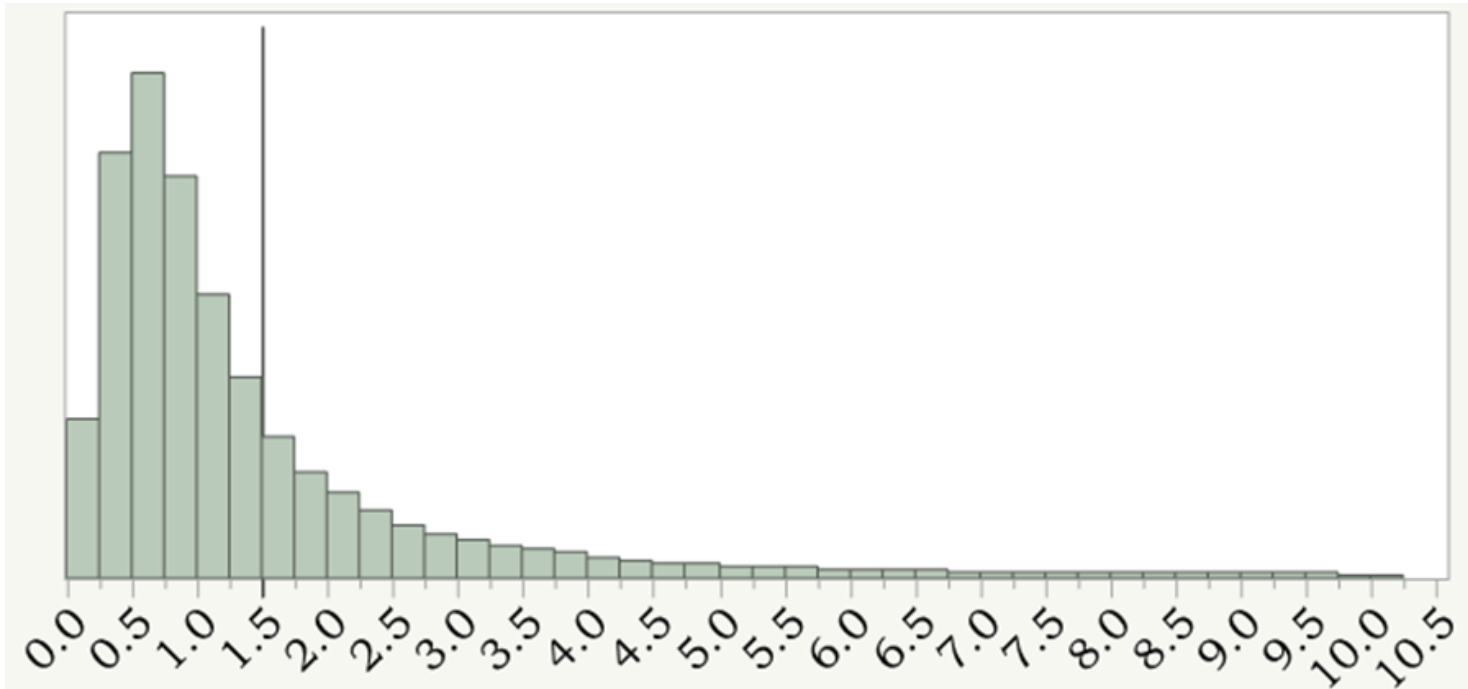
Data courtesy of Bioreference Lab

December 2015

# Screening PSAs

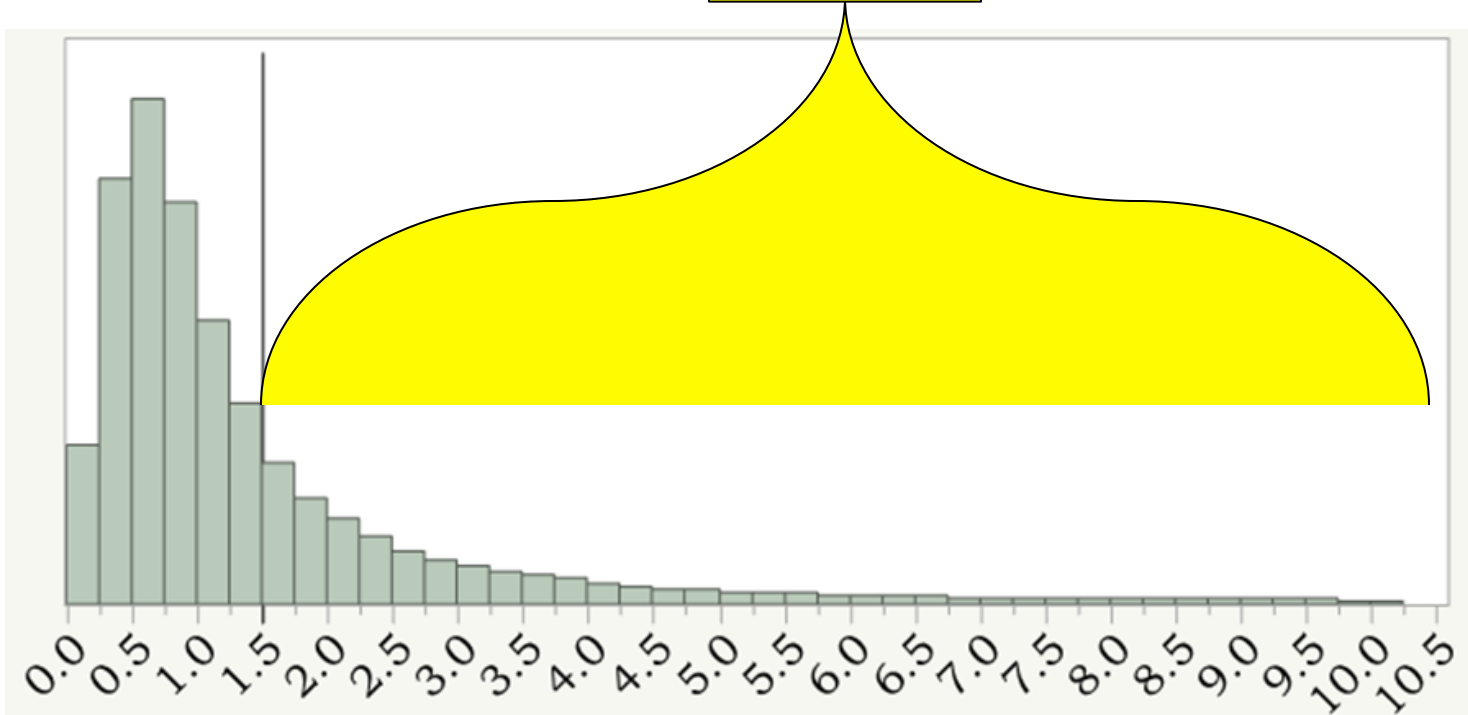
- Patients (age 40 to 75) with 1 PSA result in the past 12 months
  - 217,000 patients
  - Results from 0.01 to 5,000
- Eliminate extreme results
  - 215,613 patients
  - Results from 0.01 to 10.0

# Result Distribution



# Result Distribution

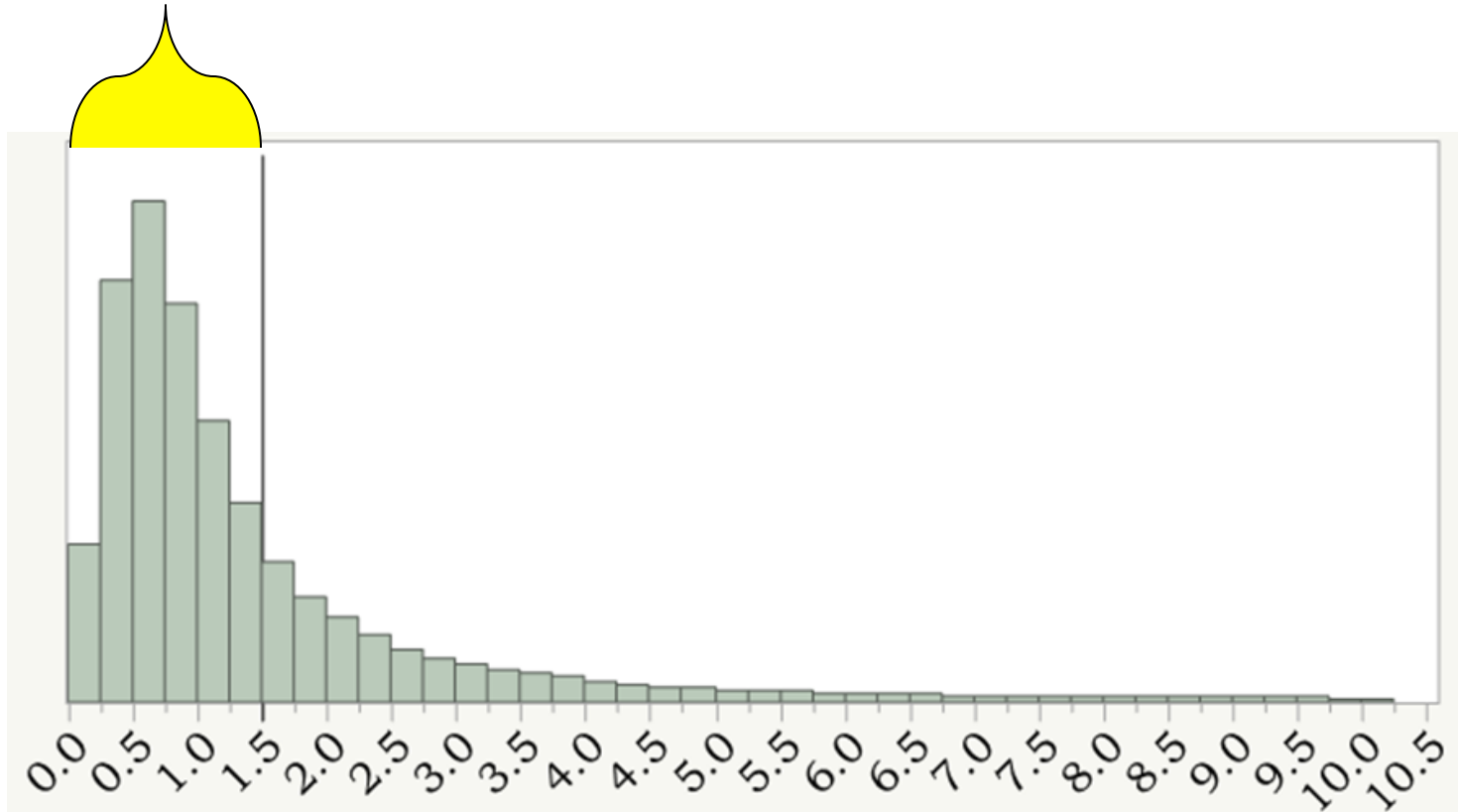
**27%**

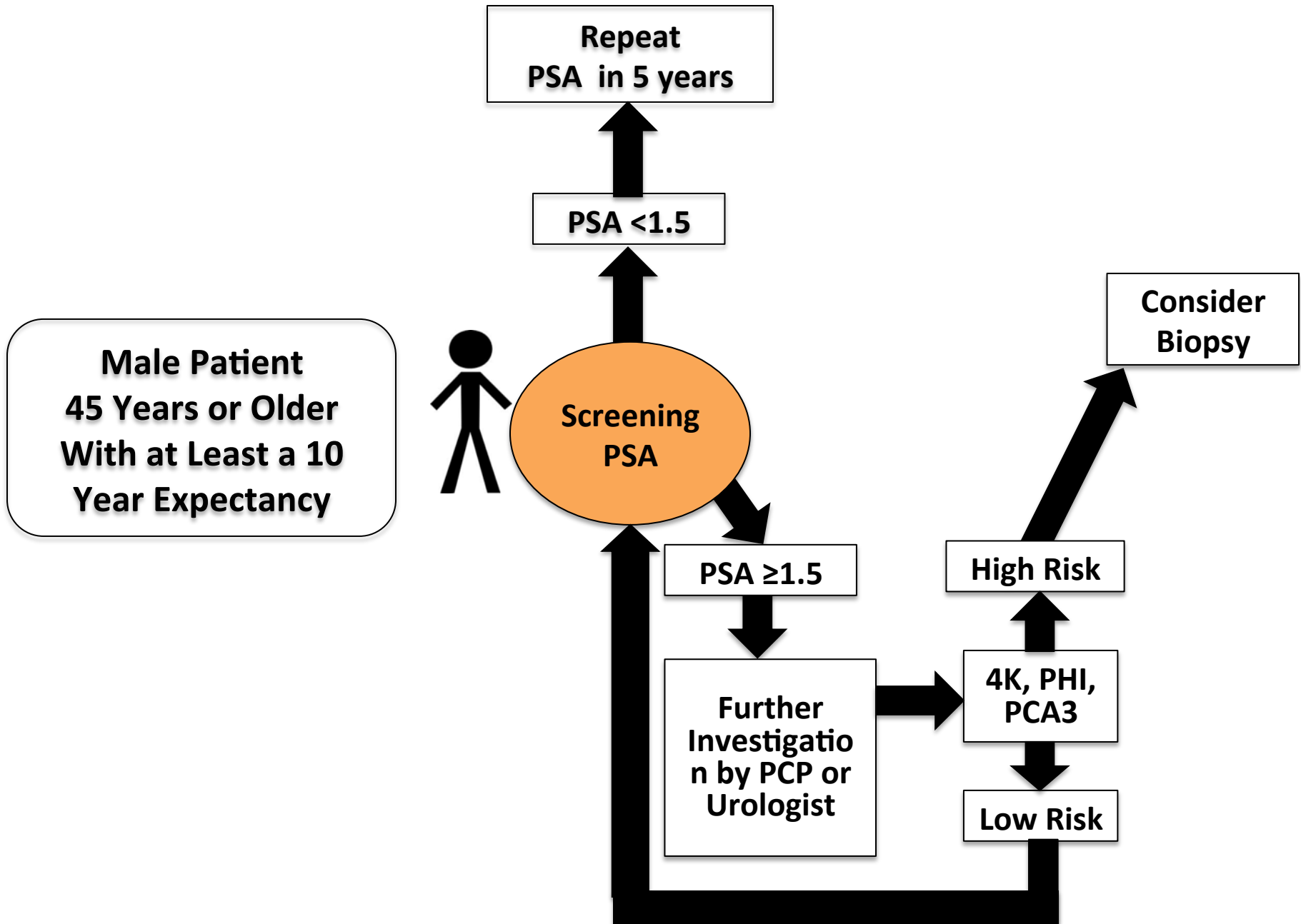




# Result Distribution

**73%**





Rosenberg MT, Spring AD, Crawford ED. IJCP 2015; in press.

# Early Detection - A Way Forward

- PSA **treated like other lab tests**, lipids, electrolytes, weight, and BP
- Shared decision making when tests **are abnormal**
  - **70%** of men require **no discussion**
- An abnormal PSA can be further evaluated with a **biomarker**

# Make Intelligent and Personalized Decisions

- Avoid PSA tests in men with little to no gain
  - Focus on age
  - Focus on health
  - Focus on quality measures
  - Focus on those at risk
- Use the PSA wisely by understanding it's value

# Logic (and Evidence) Provide the Answer



# Analogies in Primary Care

- We do not start a patient on insulin without a glycosylated A1C?
- We do not recommend cardiac bypass surgery based on an abnormal EKG?
- Does it make sense to base prostate surgery on an imperfect screening test?

# How to Make the PCP Happy

- Information for patient must be based on evidence and be beyond dispute
- Patient should be presented with a clear framework for a decision
- Process should be appropriate for primary care
  - Should not assume provider has detailed knowledge of disease
  - Should not require more than a few minutes

# How to Make the PCP Happy

- Information for patient must be based on evidence and be beyond dispute
- Patient should be presented with a clear framework for a decision
- Process should be appropriate for primary care  
**–1.5 ng/ml is simple and appropriate**



# A Call to Arms

- The urology community **MUST** take the lead in education
- Prostate cancer screening is important, if done correctly
- PSA is valuable, as a first line test
- Biomarkers improve screening by assigning risk
- Start the conversation with **1.5!!**